NOT YET SCHEDULED FOR ORAL ARGUMENT

No. 15-5015

IN THE

United States Court of Appeals for the District of Columbia Circuit

AMERICAN HOSPITAL ASSOCIATION, BAXTER REGIONAL MEDICAL CENTER, RUTLAND REGIONAL MEDICAL CENTER, AND COVENANT HEALTH,

Plaintiffs-Appellants,

v.

SYLVIA MATHEWS BURWELL, in her official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES,

Defendant-Appellee.

Appeal from the United States District Court
for the District of Columbia in
Case No.1:14-CV-851
Judge James E. Boasberg

JOINT APPENDIX

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Dated: May 4, 2015

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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BAXTER REGIONAL HOSPITAL, INC. D/B/A/
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COVENANT HEALTH
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RUTLAND HOSPITAL, INC. D/B/A RUTLAND
REGIONAL MEDICAL CENTER
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Rutland, Vermont 05701

Plaintiffs,

v.

KATHLEEN SEBELIUS, in her official capacity as
SECRETARY OF HEALTH AND HUMAN
SERVICES
200 Independence Avenue, SW
Washington, DC 20201

Defendant.

Civil Action No. 14-cv-851

COMPLAINT

Plaintiffs the American Hospital Association ("AHA"), Baxter Regional Medical Center, Covenant Health, and Rutland Regional Medical Center (collectively, "Plaintiffs") bring this mandamus complaint to compel the Secretary of Health and Human Services ("HHS") to meet the statutory deadlines for administrative review of denials of claims for Medicare reimbursement. Lengthy, systemic delays in the Medicare appeals process, which far exceed

statutory timeframes, are causing severe harm to providers of Medicare services, like the Plaintiff hospitals. HHS's unlawful delays are contrary to a clear statutory mandate requiring timely adjudication and must be eliminated.

INTRODUCTION

1. After hospitals and other healthcare providers furnish services to Medicare beneficiaries, they submit claims for payment to HHS, which processes them through the Centers for Medicare & Medicaid Services ("CMS") and its contractors. Of claims that are denied, some are denied before payment, while others are first paid and then subsequently denied during post-payment review.

2. Post-payment reviews often question the providers' medical judgment. In a growing number of cases, original payment decisions are overturned based on reviewers' findings that certain services were not medically necessary and the providers, such as Plaintiff hospitals, must pay back the funds previously reimbursed. That is so even when the review findings are incorrect.

3. Providers have a right to contest denials (whether pre- or post-payment) through a four-level appeals process within HHS. Each step of the process is governed by specific timeframes in which a decision must be rendered following receipt of the appeal.

4. Engaging in the appeals process is frequently worthwhile: When hospitals appeal the payment denials, including those made by post-payment reviewers who have a financial incentive to make findings adverse to hospitals, the decisions are very frequently reversed. Many reversals occur at the third level of the appeals process, where hospitals have a right to review of their claims by an Administrative Law Judge ("ALJ") within the HHS Office of

Medicare Hearings and Appeals ("OMHA"). This is the first opportunity for hospitals to obtain a hearing and review by an independent adjudicator.

5. Over the past several months, however, extraordinary delays in the appeals process, particularly at the ALJ level, have effectively stymied hospitals from challenging payment denials.

6. Although an ALJ's statutory deadline for holding a hearing and rendering a decision is ninety days from a hospital's filing of its appeal with OMHA, it is taking far longer than ninety days even to *docket* new requests for an ALJ hearing, let alone decide them. Indeed, currently there is a twenty to twenty-four week delay for mere docketing into the case processing system.

7. Delays at the ALJ level of the appeals process created a massive backlog of over 460,000 claim appeals by the end of 2013. At that time, the average wait for a hearing – to say nothing of a decision – was approximately sixteen months and was expected to continue to rise as the backlog grew.

8. Now the delays will be even longer still: In December 2013, OMHA announced a moratorium on assignment of provider appeals to ALJs for at least the next two years, and possibly longer. The ALJ hearing will not occur for many months after that, with a decision date likely even later. Thus, the backlog grows as new appeals come in and old ones languish: Over 480,000 claim appeals were awaiting assignment with OMHA as of February 12, 2014, with 15,000 new appeals filed each week.

9. When these excessive delays at the ALJ level are considered in conjunction with existing delays in other steps of the appeals process, the consequences are startling: hospitals will likely have to wait up to *five years*, and possibly longer, to have their claims proceed through a

four-level administrative appeals process that could otherwise conclude in less than a year according to statute.

10. The stakes for America's hospitals are high—billions of dollars in Medicare reimbursement hang in the balance. Deprived of the value of the services they already provided, hospitals are unable to use these funds to furnish patient care in their communities. For some hospitals, the situation is dire. Named Plaintiff Baxter Regional Medical Center has so much tied up in the appeals process that it cannot afford to replace a failing roof over its surgery department, purchase new beds for its Intensive Care Unit, engage in other basic upkeep, or purchase other necessary capital items.

11. Because the appeals process, as currently operating, cannot provide adequate redress, Plaintiffs have no option but to bring this mandamus lawsuit to require the Secretary's compliance with the deadlines established by law.

PARTIES

12. Plaintiff AHA is a national non-profit corporation organized and existing under the laws of the State of Illinois with offices in Chicago, Illinois, and Washington, D.C. The AHA represents more than 5,000 hospitals, health care systems, and other health care organizations, plus nearly 43,000 individual members, in matters before Congress, the executive branch, and courts. Its mission is to advance the health of individuals and communities by leading, representing, and serving the hospitals, health systems, and related organizations that are accountable to the community and committed to health improvement. The AHA provides extensive education for health care leaders and is a source of valuable information on health care issues and trends. It also ensures that members' perspectives and needs are heard in national

health policy development, legislative and regulatory debates, and judicial matters. The AHA brings this suit on behalf of its members.

13. Plaintiff Baxter Regional Medical Center ("Baxter") is a 268-bed regional hospital located in Mountain Home, Arkansas—a town of only 15,000 people. Baxter prides itself on offering a broad range of services in thirty medical specialties, including open-heart surgery, to the community it serves. Without Baxter, patients living in the surrounding counties of north-central Arkansas and south-central Missouri would need to drive two to three hours for hospital care. In 2013, Baxter was named by Moody's as America's fifth-most Medicare-dependent hospital, with Medicare responsible for sixty-five percent of its gross revenue. Baxter currently has approximately $4.6 million tied up in the Medicare appeals process, more than $1.7 million of which is pending at the ALJ level.

14. Plaintiff Covenant Health ("Covenant") is a community-owned health system located in East Tennessee, consisting of nine individual hospitals: Fort Sanders Regional Medical Center, Parkwest Medical Center, LeConte Medical Center, Methodist Medical Center of Oak Ridge, Morristown-Hamblen Healthcare System, Fort Loudoun Medical Center, Roane Medical Center (these seven hospitals collectively, "Covenant's Hospitals"), and two hospitals recently acquired in 2014. Medicare accounts for fifty-five percent of gross revenue across Covenant's Hospitals. Covenant's Hospitals have more than $7.6 million in system-wide claims pending in the Medicare appeals process, approximately $6.6 million of which is pending at the ALJ level.

15. Plaintiff Rutland Regional Medical Center ("Rutland") is a 133-bed, community-owned rural hospital located in Rutland, Vermont. Despite its small size, Rutland is the second largest hospital in the state of Vermont. It offers the full scope of community hospital services,

including an outpatient cancer center and a cardiology department, as well as uniquely important services to the community it serves, such as an outpatient drug treatment center. Rutland also took over responsibility for provision of psychiatric health care when the state's psychiatric hospital closed after flooding from Hurricane Irene. In fiscal year 2013, Medicare was responsible for approximately forty-seven percent of Rutland's gross revenues. Rutland currently has approximately $588,000 tied up in the Medicare appeals process, of which approximately $554,000 is pending at the ALJ level.

16. Defendant Kathleen Sebelius is the Secretary of HHS. This action is brought against Secretary Sebelius in her official capacity. The Secretary is responsible for implementing the Medicare program, Title XVIII of the Social Security Act, as amended, 42 U.S.C. § 1395 *et seq.* The Secretary administers the Medicare program through CMS, an agency of HHS. CMS also directs its contractors, which are responsible for the first two levels of administrative review of Medicare denials. OMHA and the Departmental Appeals Board ("DAB") within HHS provide the third and fourth levels of administrative review, respectively.

JURISDICTION

17. The Court has jurisdiction in this case pursuant to 28 U.S.C. § 1361 (jurisdiction for actions in the nature of mandamus).

VENUE

18. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(e) because this is an action against an officer of the United States in her official capacity, which is being brought in the District where the Defendant resides.

FACTUAL BACKROUND

I. The Medicare Program

19. The Medicare program was enacted in 1965 under Title XVIII of the Social Security Act to provide health insurance primarily to individuals sixty-five years of age and older. Social Security Amendments of 1965, Pub. L. 89-97, 79 Stat. 286 (1965) (codified as amended at 42 U.S.C. §§ 1395-1396v). The program's main objective is to ensure that its beneficiaries have access to health care services. *Id.* at 286. The Plaintiff hospitals qualify as providers of hospital services under Title XVIII, also known as the Medicare Act.

20. In practice, when medical providers, such as hospitals, furnish services to a Medicare beneficiary, the providers thereafter submit a claim for reimbursement to a Medicare Administrative Contractor ("MAC"). 42 U.S.C. § 1395ff(a)(2)(A). MACs are government contractors responsible for processing Medicare claims and making payments. 42 U.S.C. § 1395kk-1(a)(3).

21. Some claims that are initially paid by MACs are then subjected to an additional level of oversight. In a process known as "post-payment review," third-party contractors audit, and frequently reverse, MAC payment decisions. The post-payment review process has imposed significant burdens on the claim appeals process, particularly as the result of audits performed by one type of such contractor, known as a Recovery Audit Contractor ("RAC").

22. Permitted to audit MAC determinations on hospitals' claims dating back three years, RACs have engaged in wide-ranging audits that often question the medical judgment of the hospital and admitting physician. It is in the RACs' interests to do so: RACs themselves are paid based on the amount of Medicare reimbursement they recover from hospitals for purportedly "improper" payments. Thus, RACs have an incentive to overturn MAC payment

decisions, particularly for more expensive services. One of the most common – and very lucrative – bases for a RAC reversal of a MAC's payment determination is a finding that a hospital billed for an inpatient hospital stay when, in the RAC's view, appropriate care could have been provided on an outpatient hospital basis.

23. Aggressive and widespread auditing activity by the RACs predictably has affected the number of hospital claim appeals. An increasingly large percentage of the cases received by OMHA results from RAC appeals. *See* OMHA Medicare Appellant Forum Presentation at 108 (February 12, 2014), *available at* http://www.hhs.gov/omha/omha_medicare_appellant_forum.html (last visited May 22, 2014) (hereinafter "OMHA Forum Presentation"). For example, in fiscal year 2009, the last full fiscal year before the permanent RAC program was instituted, there were 35,831 appeals filed with OMHA for ALJ review. *Important Notice Regarding Adjudication Timeframes*, Office of Medicare Hearings and Appeals, U.S. Department of Health & Human Services, available at http://www.hhs.gov/omha/important_notice_regarding_adjudication_timeframes.html (last visited May 22, 2014) ("*Important Notice*"). In comparison, in fiscal year 2013, well after the implementation of the RACs, 384,651 appeals were filed—more than ten times as many as only four years earlier. *Id.*; *see also* OMHA Forum Presentation at 16. The value of appealed, RAC-denied claims alone is well over $1 billion. *See* AHA, Exploring the Impact of the RAC Program on Hospitals Nationwide, at 47 (June 1, 2013), *available at* http://www.aha.org/content/13/13q1ractracresults.pdf.

24. RAC claim denials are frequently overturned on appeal. According to data provided to the AHA through the first quarter of 2013, hospitals reported that when they

appealed RAC denials, including up to an ALJ, the denials were overturned seventy-two percent of the time. *Id.* at 55.

II. The Appeals Process

25. Appeals of both pre- and post-payment claim denials are subject to a four-step process, set forth by statute. *See* 42 U.S.C. § 1395ff. The first two steps of the process are overseen by CMS; the third is overseen by OMHA; and the fourth is overseen by the DAB. The steps are as follows:

a. A denied claim is first presented to the MAC for redetermination. *Id.* § 1395ff(a)(3)(A). In cases of a RAC denial following an initial MAC approval, the hospital presents the RAC-denied claim to the MAC that originally approved and paid the claim. The MAC must render a redetermination decision within sixty days. *Id.* § 1395ff(a)(3)(C)(ii).

b. If unsatisfied with the MAC's redetermination, a hospital can appeal the MAC's decision to a Qualified Independent Contractor ("QIC") for reconsideration. *Id.* § 1395ff(c). QICs are tasked with independently reviewing the MAC's determination and must render a decision within sixty days. *Id.* § 1395ff(c)(3)(C)(i).

c. Provided that the amount in controversy is greater than $140 (for calendar year 2014), a hospital may next request a hearing before an ALJ. *Id.* §§ 1395ff(b)(1)(E), 1395ff(d)(1)(A). Review by an ALJ is the first opportunity for independent review of a claim. The ALJ is required both to hold a hearing and to render a decision within ninety days. *Id.*; 42 C.F.R. § 405.1016(a). When they have been granted the hearing required by law, this is the level of the appeals process at which hospitals typically have been able to obtain relief from adverse RAC determinations.

d. Finally, a hospital can appeal its claim to the DAB. *Id.* § 1395ff(d)(2); 42 C.F.R.§ 405.1108(a). In that event, the DAB conducts a *de novo* review of the ALJ decision and either renders its own decision or remands to the ALJ for further proceedings. *Id.* In either event, the DAB must act within ninety days. *Id.*

26. There is also a separate "escalation" process applicable to the QIC, ALJ and DAB levels of review.

a. Specifically, if the QIC is unable to complete its review within sixty calendar days, it must notify all parties that it cannot complete the reconsideration within the statutory timeframe and offer the hospital the opportunity to "escalate" the appeal to an ALJ. 42 U.S.C. § 1395ff(c)(3)(C)(ii); 42 C.F.R. § 405.970. The QIC will continue the reconsideration process unless and until the hospital files a written escalation request. 42 C.F.R. § 405.970(c)(2).

b. Similarly, if an ALJ has not held a hearing and rendered a decision within ninety days, a hospital may bypass the ALJ level by escalating its claim to the DAB. 42 U.S.C. § 1395ff(d)(3)(A). In such situations, the QIC's decision becomes the decision subject to DAB review. 42 C.F.R. § 405.1104; 42 C.F.R. § 405.1108(d). That means that if the hospital has previously escalated from the QIC, only the record before the MAC is available for review. The DAB may conduct additional proceedings, including a hearing, but (unlike at the ALJ level) is not required to do so. 42 C.F.R. § 405.1108. In fact, OMHA has explained that, in escalation situations, the DAB will "NOT hold a hearing or conduct oral argument unless there is an extraordinary question of law/policy/fact." OMHA Forum Presentation at 117. The DAB has 180 days in which to act on an escalation request, rather than its usual ninety. 42 C.F.R. § 405.1100(c)-(d).

c. Likewise, if the DAB has not rendered a decision within ninety days on its

review of an ALJ's decision, a hospital may bypass the DAB and seek judicial review. 42 U.S.C. § 1395ff(d)(3)(B); 42 C.F.R. § 405.1132. In cases of an initial escalation past the ALJ level, a hospital may escalate the appeal to federal court if the DAB fails to render a decision within 180 days. 42 C.F.R. § 405.1132; 42 C.F.R. § 405.1100(d). In the event of this "double escalation," the only agency decision available to the federal court for review is the QIC's decision, made without a hearing. In the event of a "triple escalation" (from the QIC, from the ALJ, and from the DAB), only the MAC record is available for review.

III. The Delay

27. The statutory time periods governing the appeals process provide for all levels of administrative review to be completed within about one year. In practice, however, the time it takes to pursue a claim appeal through HHS far exceeds the timeframes established by the Medicare Act.

28. The moratorium declared by OMHA on assignment of appeals to ALJs will only exacerbate this problem, causing the DAB – and potentially the federal courts – to be inundated with claim appeals that never have received the benefit of a hearing

A. *The ALJ Backlog*

29. Enormous increases in the rates of appeal, in significant part by providers challenging inappropriate denials by over-zealous RACs, have caused a massive backlog at the ALJ level of the appeals process. In just two years (2012 and 2013), the backlog of ALJ-level appeals *quintupled*, growing from 92,000 to 460,000 pending claims. Ex. 1, Memorandum from Nancy J. Griswold, Office of Medicare Hearings & Appeals, Chief Admin. Law Judge, to OMHA Medicare Appellants (Dec. 24, 2013) ("Griswold Memorandum").

30. The ALJs simply have not kept up with the prodigious and growing volume of appeals. The workload of OMHA's sixty-five ALJs increased by almost 300% from fiscal year 2012 to fiscal year 2013. *See* OMHA Forum Presentation at 16. In fiscal year 2013, of the 384,651 appeals that were filed, only 79,303 were decided – a meager twenty-one percent. OMHA Forum Presentation at 12 (reflecting decision figures); *Important Notice* (reflecting adjusted appeals receipts figures).

31. Indeed, as of December 2013, appeals had languished for an average of sixteen months – approximately thirteen months longer than the ninety-day statutory deadline for a *decision* – before an ALJ even *heard* the case. OMHA Forum Presentation at 11; s*ee* Ex. 1 (Griswold Memorandum).

32. The backlog of appeals, and concomitant delay in adjudication, has reached a crisis point. On December 24, 2013, OMHA's Chief ALJ, Nancy Griswold, announced that OMHA had suspended the assignment of all new provider appeals to ALJs, apparently as of July 15, 2013. Ex. 1 (Griswold Memorandum). The suspension is expected to last for a minimum of two years, with additional post-assignment hearing wait times expected to exceed six months when the suspension is eventually lifted. *Id*. As recently as February 14, 2014, Judge Griswold conceded that the wait times for a hearing before an ALJ are unacceptable. Michelle M. Stein, *ALJs Lay Out Path Forward For Stakeholders As Appeals Backlog Continues*, INSIDE HEALTH POLICY, Feb. 14, 2014, *available at* http://insidehealthpolicy.com/201402142461310/Health-Daily-News/Daily-News/aljs-lay-out-path-forward-for-stakeholders-as-appeals-backlog-continues/menu-id-212.html (last visited May 22, 2014).

33. The situation is getting only worse. OMHA received more than 15,000 appeals per week in February 2014. OMHA Forum Presentation at 53. OMHA has stated that it is currently projecting a twenty to twenty-four week delay even in *docketing* new appeals. *Important Notice*. From there, the new appeals will await assignment indefinitely, while the moratorium persists. As of February 12, 2014, 480,000 appeals were awaiting assignment to an ALJ. OMHA Forum Presentation at 57. And OMHA's self-imposed suspension in processing of appeals does not alter the requirement that a provider appeal an unfavorable QIC decision within sixty days, meaning that the backlog at the ALJ level will increase dramatically as appeals continue to roll in without being assigned or decided. *See* 42 U.S.C. § 1395ff(b)(1)(D)(ii); 42 C.F.R. § 405.1014(b)(1).

34. The more than two-year moratorium on assignment of new appeals to an ALJ, taken together with the likely additional wait times for assignment even after the moratorium is lifted and the predicted wait times to obtain a hearing once a case is assigned to an ALJ, means hospitals lodging new appeals from the QIC to the ALJ can realistically expect to wait close to three years, and probably longer, even to *obtain an ALJ hearing* – let alone to receive a decision. *See Important Notice*; Ex. 1 (Griswold Memorandum).

B. *The DAB Backlog*

35. The DAB – the last level of administrative review – is similarly inundated. At the end of fiscal year 2013, the DAB had 4,888 pending appeals, 112% more than it had at the end of fiscal year 2012. OMHA Forum Presentation at 106. OMHA projects that 7,000 DAB appeals will be received in fiscal year 2014. *Id.* That number is expected to rise to over 8,000 for fiscal year 2015. *Id.* As with the ALJs, the DAB is seeing an increased caseload due to the behavior of the RACs and other Medicare contractors.

36. OMHA itself recognizes that, like the ALJs, the DAB cannot keep up with the dramatic increase in appeals. It has conceded that the DAB is "unlikely to meet the 90-day deadline for issuing decisions in most appeals." OMHA Forum Presentation at 110.

37. This concession does not even account for the increase in escalated cases the DAB will receive, where an ALJ has failed to render any decision and the DAB is forced to remand the case or begin and conclude adjudication from scratch, with only the record from the QIC (or potentially even from the MAC) as a basis for review.

38. Even if the DAB could find a way to adjudicate all of the appeals pending before it, it is not equipped to conduct the full hearing that would otherwise occur at the ALJ level in escalated cases. There are just *four* Appeals Officers within the DAB responsible for final administrative review of Medicare entitlement, managed care, and prescription drug claims in addition to the hundreds of thousands of claims from providers such as Plaintiff hospitals challenging fee-for-service payment denials. OMHA Forum Presentation at 103-104. And publicly available information about the DAB's actions in escalated cases reveals that it has not conducted a hearing in any of them.

39. Instead, the DAB can take one of only four actions, all of which are inadequate. First, it may render a summary decision on the basis of only the record established before the QIC (or, in the case of a triple escalation, the MAC), which would not provide the due process contemplated by the statute, in the form of an ALJ hearing. 42 U.S.C. § 1395ff(d)(1)(A). Second, it may remand the appeal to the ALJ, which would place the hospitals in the same position in which they started, waiting years for a relatively small number of ALJs to wade through an enormous and increasing backlog of appeals, only now at the back of the ALJ line. Third, the DAB may issue a notice that it, too, is unable to fulfill its statutory duty within the

required timelines and thereby allow hospitals to escalate their claims to federal court. Or fourth, it may do nothing at all.

C. *Impending Federal Court Involvement*

40. Given the immense backlog at the ALJ level and the expected attendant increase in escalations to the DAB, itself already backlogged, hospitals are put to the difficult question whether to escalate their claims from the DAB to federal court, which cannot provide an adequate remedy in any event due to the lack of a meaningful administrative record upon which to base a decision.

41. Under the regulations, a hospital may file an action in federal district court if the DAB notifies it that no decision will be issued and if its claim meets an amount-in-controversy requirement (currently $1,430). 42 C.F.R. § 405.1132(b); 42 C.F.R. § 405.1006(c); Notice of Adjustment to the Amount in Controversy Threshold Amounts for Calendar Year 2014, 78 Fed. Reg. 59702-03 (Sept. 27, 2013). Hospitals having claims that do not meet the amount-in-controversy requirement for escalation must simply wait out the delays at the agency level.

42. Those that do meet the amount-in-controversy requirement must decide whether to undertake an attempt at escalation. As an initial matter, escalation may be thwarted by the DAB: The DAB may prevent escalation to federal court by remanding the claim to the ALJ level, 42 C.F.R. §405.1108(d)(3), where the claim will languish in a futile loop of escalation and remand. Under that scenario, hospitals that attempt to escalate may instead merely forfeit their position in the ALJ queue.

43. Alternatively, if the DAB permits escalation to federal court by providing notice that it will not issue a decision, hospitals must face the dilemma of whether to wait out the

lengthy administrative review delays or incur the cost of a federal court lawsuit that is neither an adequate remedy nor a viable alternative.

44. Federal court escalation is not an adequate remedy for Plaintiffs and other hospitals because (a) an escalating Plaintiff or other hospital will have had no hearing as contemplated by the Medicare Act; and (b) the court will have before it only the record and determination made by the QIC (or the MAC) without a hearing and will lack the benefit of an independent ALJ's findings of fact and conclusions of law.

45. In view of the undeveloped record before the federal court in the event of "double- or triple- escalation," because neither the ALJ nor the DAB (and possibly not even the QIC) rendered a timely decision on a hospital's claim, the federal court might remand the matter to the agency for fact-finding. This result would leave Plaintiffs and other hospitals stuck in an endless loop of escalation and remand with no meaningful opportunity to be heard and no merits decision.

46. Further, the cost of litigating claims in federal court may render escalation worthless in many cases. Because the amount-in-controversy requirement for escalation to federal court is relatively low, hospitals must weigh the cost of federal court litigation against the total possible recovery. In circumstances in which hospitals would pay more to litigate their claims than they could even recover, federal court escalation is not a viable alternative for Plaintiffs and other hospitals. They are thus left with no adequate remedy for HHS's unlawful delays.

III. The Impact of the Backlog on Hospitals

47. Hospitals are suffering nationwide under HHS's refusal to render decisions on appeals in a timely manner. Whether claims denials are pre-payment – in which case hospitals

never receive payment for the value of their services – or post-payment – in which case hospitals must repay the amount initially reimbursed before they ever get to the ALJ level – hospitals are deeply out-of-pocket for services they already have rendered.

48. The deprivation of funds tied up in the appeals process is a profound problem. These are funds that otherwise could be dedicated to patient care or to sustaining the hospital infrastructure necessary to provide patient care. The delays in the system strain the cash flows of hospitals, many of which are already cash-strapped. HHS's delay in meeting the statutory Medicare claim appeal deadlines thus presents a serious threat to hospitals nationwide and their ability to continue to provide quality patient care while maintaining financial viability.

49. The Plaintiff hospitals have numerous claim denials delayed at various stages of the appeals process. The delays, and the concomitant deprivation of funds, have caused and are continuing to cause severe harm to the Plaintiff hospitals.

A. *Baxter*

50. Plaintiff Baxter currently has 144 claims at the ALJ level of the appeals process, of which 133 have been filed since July 15, 2013 and thus are subject to the moratorium on assignment of appeals to an ALJ. Thirty-eight appeals, accounting for more than $337,000 in Medicare reimbursement, have been pending at the ALJ for longer than ninety days. All told, more than $1.7 million in reimbursement for services that Baxter provided to Medicare beneficiaries is tied up at the ALJ level of the appeals process.

51. The delays in the appeals process have had a crippling effect on Baxter's cash flow. Funds tied up in appeals are funds that cannot be used to meet Baxter's essential needs. For example, the hospital has not been able to purchase basic equipment, like beds for its Intensive Care Unit. Instead of replacing a failing roof over its surgery department, Baxter has

been able only to patch it. The costs of Baxter's voluminous appeals of rehabilitation-related claim denials, combined with the delay in achieving resolution of those claims, has become so prohibitive that Baxter has considered whether it would be more financially prudent to *close* its rehabilitation center rather than to pursue the appeals.

B. *Covenant*

52. Covenant's Hospitals have approximately 1388 appeals currently pending at the ALJ level, of which approximately 812 have been filed since July 15, 2013 and are subject to the moratorium on ALJ assignment, and approximately 1350 have been pending for longer than ninety days.

53. The delays in adjudicating these pending appeals have significantly impaired Covenant's cash flow as it tries to "do more with less" across its system. Funds tied up in the appeals process are not available for allocation among Covenant's Hospitals to address patient care needs in the various communities those hospitals serve. Covenant, like Baxter, has considered whether, in light of the severe ALJ delay, it is financially prudent to continue to offer the full scope of rehabilitative services to the entire population of patients it currently serves.

C. *Rutland*

54. Rutland currently has 98 appeals pending at the ALJ level, of which 54 are newly-filed appeals that are subject to the moratorium on ALJ assignment and 7 are appeals that have been pending for longer than ninety days. These pending appeals represent more than a half a million dollars in Medicare reimbursement for services that Rutland provided to its patients.

55. These are funds that Rutland could be using to advance its mission, but instead are held up in the ALJ delay. Rutland also has had to implement a number of cost-cutting

measures in the wake of the ALJ delay to accommodate the cash flow deficiencies caused by the delay.

V. HHS Has Not Resolved The Unlawful Delays.

56. Despite public outcry and mounting pressure from the wide range of medical providers harmed by the unlawful delays, HHS has not taken action to remedy the situation.

57. Prior to bringing this lawsuit, Plaintiff AHA sent a letter to CMS – responsible for the first and second levels of administrative review – urging it to cooperate with OMHA to remedy the backlog, noting that the moratorium is "a direct violation of [the] Medicare statute that requires ALJs to issue a decision *within 90 days of receiving the request for hearing*." Letter from Rick Pollack, Executive Vice President of AHA, to Marilyn Tavenner, Administrator of CMS (January 14, 2014), *available at* www.aha.org/letters/2014?&p=8 (last visited May 22, 2014).

58. On February 12, 2014, ninety-eight organizations sent a letter to Chief ALJ Griswold, "urg[ing] OMHA to develop a comprehensive solution to the Medicare appeal backlog problem" because "[t]he numerous appeals requirements, actual costs of filing appeals, and often lengthy delays undermine the ability of physicians to deliver patient-centered care." Letter from the American Medical Association, et al., to The Honorable Nancy J. Griswold, Chief Administrative Law Judge, Office of Medicare Hearings and Appeals (February 12, 2014), *available at* http://www.aafp.org/dam/AAFP/documents/advocacy/payment/medicare/LT-HHS-MedicareAppealsBacklog-021214.pdf.

59. On March 27, 2014, the Advanced Medical Technology Association ("AdvaMed") wrote to Defendant Sebelius and to the Administrator of CMS to express its concerns about the moratorium, explaining that "the policy will create significant harm for both

patients and providers." Letter from Donald May, Executive Vice President of Payment & Healthcare Delivery Policy at AdvaMed, to Kathleen Sebelius, Secretary of HHS, and Marilyn Tavenner, Administrator of CMS, at 1 (March 27, 2014), *available at* http://advamed.org/res/472/office-of-medicare-hearing-and-appeals-decision-to-suspend-assignment-of-new-request-for-administrative-law-judge-hearings-for-adjudication-of-appeals (last visited May 22, 2014). AdvaMed criticized OMHA's moratorium as "plainly violat[ing] the statute and contradict[ing] the purpose of the Medicare appeals process," and noted that the moratorium only "perpetuates the backlog that eliminates the statutory schedule of appeal reviews." *Id.* at 2.

60. Yet the moratorium remains in place. The ALJ backlog problem is egregious and growing more so as appeals continue to mount without resolution by HHS. OMHA has admitted that it is not meeting its statutory deadlines and will not be able to do so any time in the near future. In the meantime, hospitals are deprived of crucial funds and stuck in endless administrative holding patterns or forced to opt out of the only meaningful opportunity for hearing by undertaking attempts at escalation.

COUNT I
Relief Under the Mandamus Act (28 U.S.C. § 1361)

61. Plaintiffs reallege and incorporate herein by reference all of the allegations contained in paragraphs 1 through 60 above as if fully set forth herein.

62. The Mandamus Act, 28 U.S.C. § 1361, vests district courts with original jurisdiction over any action in the nature of mandamus to compel an officer or employee of the United States or any agency thereof to perform a duty owed to Plaintiffs.

63. Under federal law, HHS has a clear, indisputable, and non-discretionary duty to "conduct and conclude a hearing on a decision of a qualified independent contractor . . . and

render a decision on such hearing by not later than the end of the 90-day period beginning on the date a request for hearing has been timely filed." 42 U.S.C. §1395ff(d)(1)(A).

64. HHS has breached this duty by acting in derogation of statute by, *inter alia*, permitting its delegee, OMHA, to suspend the assignment of all new provider appeals to ALJs for a minimum of twenty-four months and by failing to hold hearings and render decisions within ninety days at the ALJ level.

65. HHS's delays throughout the appeals process, and most notably at the ALJ level, plainly violate the timetables set forth by Congress in the Medicare Act.

66. HHS's delays in resolving Medicare appeals affect human health and welfare by compromising the economic well-being of hospitals across the country.

67. Absent mandamus, Plaintiffs have no adequate remedy. Neither the DAB nor the federal district courts can provide an adequate remedy to Plaintiffs. The escalation process does not provide a meaningful option for the reasons alleged above, including, *inter alia*, because it deprives Plaintiffs of their right to a hearing, while imposing costs that threaten the very value of the remedy Plaintiffs seek.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court:

(a) enter a declaratory judgment that HHS's delay in adjudication of Medicare appeals violates federal law;

(b) enter an order:

(i) requiring HHS forthwith to provide Baxter Regional Medical Center, Covenant Health, and Rutland Regional Medical Center the hearing before an ALJ and ALJ decision

required by law in each of their claim appeals pending at the ALJ level for ninety days or more;

(ii) requiring HHS forthwith to provide Baxter Regional Medical Center, Covenant Health, and Rutland Regional Medical Center the resolution required by law in each of their claim appeals pending at the DAB for ninety days or more; and

(iii) requiring HHS to otherwise comply with its statutory obligations in administering the appeals process for all hospitals;

(c) enter a judgment for costs and reasonable attorney's fees pursuant to 28 U.S.C. § 2412; and

(d) grant such other relief at law and in equity as justice may require.

Respectfully submitted,

HOGAN LOVELLS US LLP

Dated: May 22, 2014

By: /s/ Adam K. Levin

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Mitchell E. Zamoff (D.C. Bar No. 439383)
Adam K. Levin (D.C. Bar No. 460362)
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Attorneys for Plaintiffs

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office of the Secretary

Office of Medicare Hearings and Appeals
Office of the Chief Judge
1700 North Moore Street, Suite 1800
Arlington, VA 22209
(703) 235-0635 Main Line
(703) 235-0700 Facsimile

DEC 2 4 2013

Memorandum to OMHA Medicare Appellants

Re: Administrative Law Judge Hearings for Medicare Claim and Entitlement Appeals

Based on a number of recent inquiries regarding delays in the processing of Medicare claim and entitlement appeals, I want to apprise you of some recent operational changes that may impact your interaction with the Office of Medicare Hearings and Appeals (OMHA). You have been chosen to receive this letter because you have a significant number of Medicare appeals currently pending before OMHA.

Due to the rapid and overwhelming increase in claim appeals, effective July 15, 2013, OMHA temporarily suspended the assignment of most new requests for an Administrative Law Judge hearing to allow OMHA to adjudicate appeals involving almost 357,000 claims for Medicare services and entitlements already assigned to its 65 Administrative Law Judges. This temporary measure was necessitated by a dramatic increase in the number of decisions being appealed to OMHA, the third level of administrative review in the Medicare claim and entitlement appeals process.

From 2010 to 2013, OMHA's claims and entitlement workload grew by 184% while the resources to adjudicate the appeals remained relatively constant, and more recently were reduced due to budgetary sequestration. Even with increased productivity from our dedicated Administrative Law Judges and their support staff, we have been unable to keep pace with the exponential growth in requests for hearing. Consequently, a substantial backlog in the number of cases pending an ALJ hearing, as well as cases pending assignment has resulted.

In just under two years, the OMHA backlog has grown from pending appeals involving 92,000 claims for services and entitlement to appeals involving over 460,000 claims for services and entitlement, and the receipt level of new appeals is continuing to rise. In January 2012, the number of weekly receipts in our Central Operations Division averaged around 1,250. This past month, the number of receipts was over 15,000 per week. Due to this rapidly increasing workload, OMHA's average wait time for a hearing before an Administrative Law Judge has risen to 16 months and is expected to continue to increase as the backlog grows.

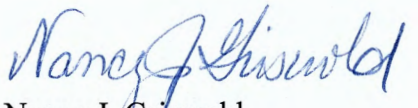
Although assignment of most new requests for hearing will be temporarily suspended, OMHA will continue to assign and process requests filed directly by Medicare beneficiaries, to ensure their health and safety is protected. Assignment of all other new requests for hearing will resume as Administrative Law Judges are able to accommodate additional workload on their dockets. However, with the current backlog we do not expect general assignments to resume for at least 24 months and we expect post-assignment hearing wait times will continue to exceed 6 months.

We remain committed to providing a forum for the fair and timely adjudication of Medicare claim and entitlement appeals; however, we are facing significant challenges which reduce our ability to meet the timeliness component of our mission. To address this challenge, OMHA is working closely with our colleagues within the Centers for Medicare and Medicaid Services (CMS) and the Departmental Appeals Board (DAB). We are committed to finding new ways to work smartly and more efficiently, in order to better utilize resources to address the increased demand for hearings.

In order to keep you apprised concerning our workload and to facilitate your interaction with OMHA, we will host an OMHA Medicare Appellant Forum on February 12, 2014, from 10:00 am to 5:00 pm. The event will take place in the Wilbur J. Cohen building located at 330 Independence Ave. SW, Washington DC 20024. The purpose of this event is to provide further information to OMHA appellants and providers on a number of initiatives underway and to provide information on measures we can take to make the appeals process work more efficiently. You can obtain further information and register for the event by visiting the OMHA website; http://www.hhs.gov/omha/index.html. We are pleased to offer this opportunity and hope you will be able to join us.

Although we know that this information will not alleviate your concerns with regard to delays in processing appeals, we hope that we have at least provided a backdrop for the environment in which OMHA currently processes appeals. We ask for your indulgence as we work to address these challenges and thank you in advance for your patience as we continue our efforts to serve the Medicare appellant and beneficiary communities. For additional information and updates on OMHA's adjudication timeframes, or to register for our OMHA Medicare Appellant Forum, please visit the OMHA website at: http://www.hhs.gov/omha/index.html.

Sincerely,



Nancy J. Griswold
Chief Administrative Law Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN HOSPITAL ASSOCIATION, *et al.*, Plaintiffs, v. SYLVIA MATHEWS BURWELL, in her official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES, Defendant.	Civil Action No. 1:14-CV-851-JEB

PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Pursuant to Rule 56 of the Federal Rules of Civil Procedure and Rule 7(h) of the Rules of the United States District Court for the District of Columbia, Plaintiffs the American Hospital Association, Baxter Regional Medical Center, Covenant Health, and Rutland Regional Medical Center (collectively, "Plaintiffs," and Baxter, Covenant, and Rutland collectively, the "Plaintiff hospitals") respectfully submit this motion for summary judgment on their mandamus claim against Defendant Sylvia Mathews Burwell, Secretary of Health and Human Services ("HHS").

As explained more fully in the accompanying Memorandum of Points and Authorities, which is incorporated by reference herein, Plaintiffs bring this action to remedy unlawful delays in HHS's adjudication of Medicare claim appeals. Systemic delays within the four-step administrative appeals process are postponing by years the adjudications to which providers like Plaintiff hospitals are entitled by statute. Most significantly, although the Medicare Act provides for hearing and adjudication by an Administrative Law Judge ("ALJ") at the third level of appeal within ninety days, it currently is taking well over a year for such adjudications to occur. The length of delay will further increase because on December 24, 2013, HHS announced that it had

become so backlogged at the ALJ level that, effective July 15, 2013, it had imposed a moratorium on the assignment of new claim appeals to ALJs for hearing that is expected to last a minimum of two years.

HHS's delays violate the clear timetables set forth by Congress in the Medicare Act, 42 U.S.C. §§1395-1396v, are egregious and unreasonable, and should be remedied. The delays are causing severe harm to providers of Medicare services, like the Plaintiff hospitals, which cannot recover the Medicare reimbursement to which they are entitled for claims that were improperly denied.

Plaintiffs' claims are appropriate for summary judgment because they are grounded in statutory mandates and facts publicly conceded by HHS. As a matter of law and undisputed fact, the Court should grant mandamus relief and require the Secretary of HHS to comply with the statutory deadlines for the Medicare claim appeals process.

Dated: July 11, 2014

Respectfully Submitted,

/s/ Adam K. Levin
Sheree R. Kanner (D.C. Bar No. 366926)
Mitchell E. Zamoff (D.C. Bar No. 439383)
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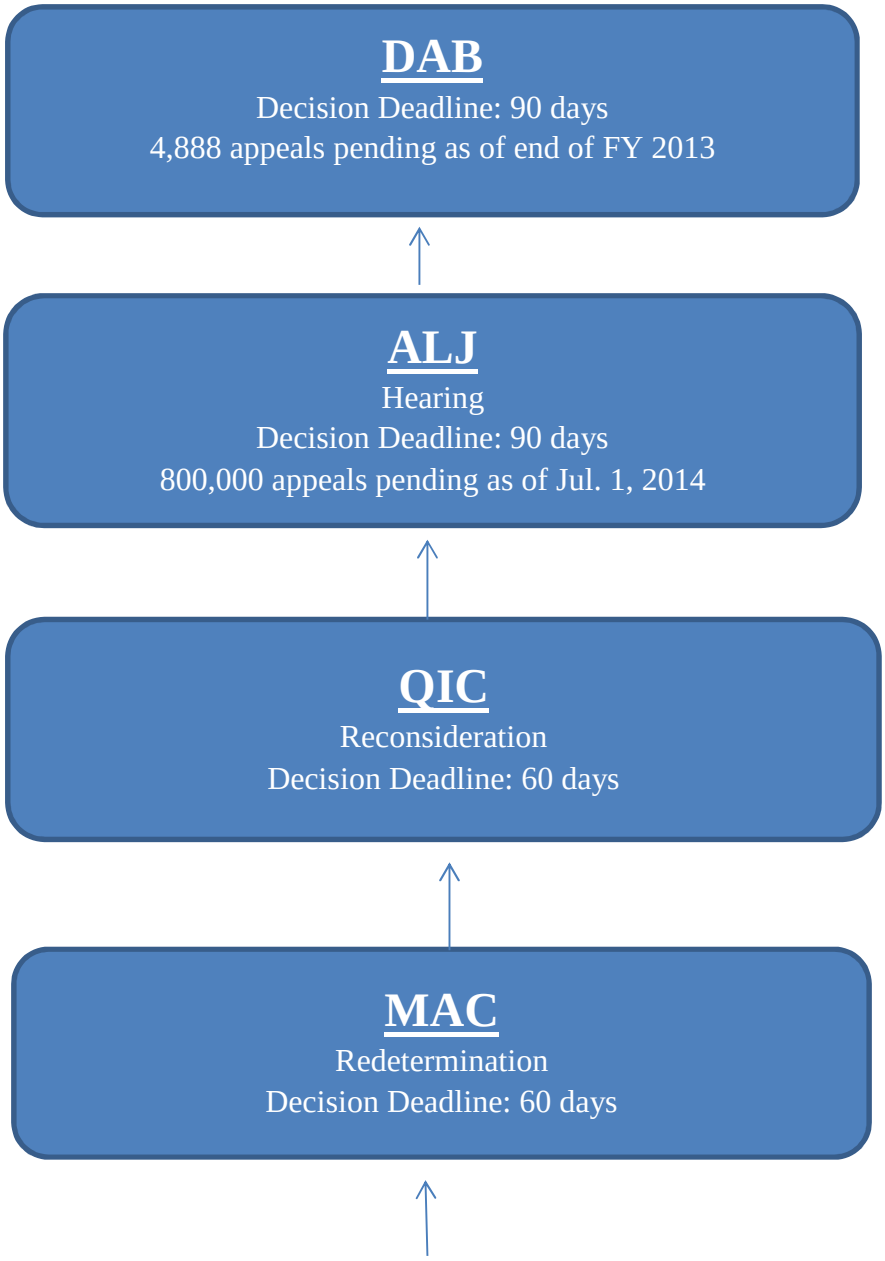
Medicare Administrative Appeals Process



Source: 42 U.S.C. §1395ff; Ex. 2 (OMHA Forum Presentation); Ex. 7 (Griswold Statement, Jul. 10, 2014)

Office of Medicare Hearings and Appeals

Medicare Appellant Forum

Wednesday, February 12, 2014

Welcome

Please stand-by --the Forum will begin promptly at 10:00 a.m.

Please
Be in your seats at start time
Mute your phone or place in vibrate mode
Do not bring any food or drinks into the auditorium

Departmental Appeals Board Update
Medicare Appeals Council

Judge Constance B. Tobias
Chair, HHS Departmental Appeals Board
Department of Health and Human Services

Office of Medicare Hearings and Appeals (OMHA) – Medicare Appellant Forum – February 12, 2014 – Washington, D.C.

DEPARTMENTAL APPEALS BOARD (DAB)

The DAB is a 76-person umbrella organization, located within the Office of the Secretary and comprised of:

- Departmental Appeals Board Members
- Civil Remedies Division Administrative Law Judges
- Medicare Appeals Council
- Alternative Dispute Resolution Division

MEDICARE APPEALS COUNCIL

The Medicare Appeals Council (Council) is comprised of:

- Board Chair
- Administrative Appeals Judges
- Appeals Officers
- Members of the Departmental Appeals Board (if necessary)

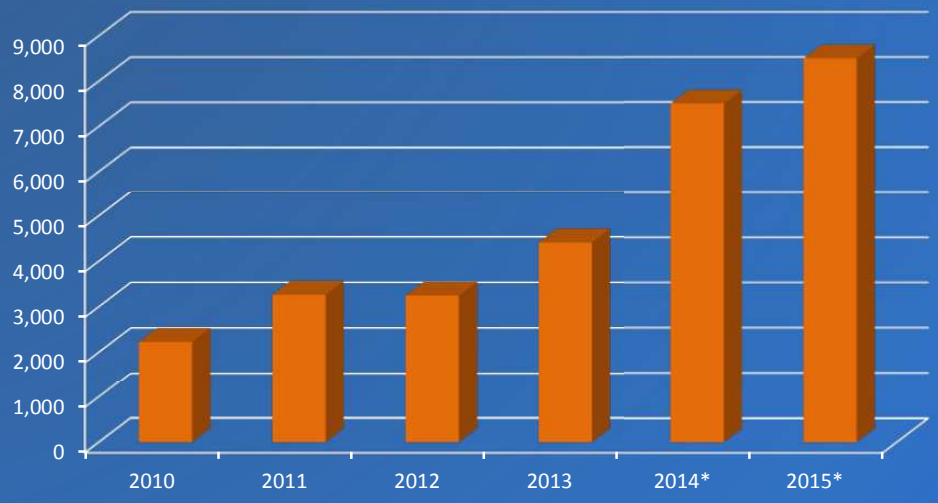
The Council provides the final administrative review for:

- Medicare entitlement
- Fee-for-service claims
- Managed care or prescription drug claims

The Council is supported by the Medicare Operations Division (MOD) attorneys and support staff.

MOD WORKLOAD PROJECTIONS

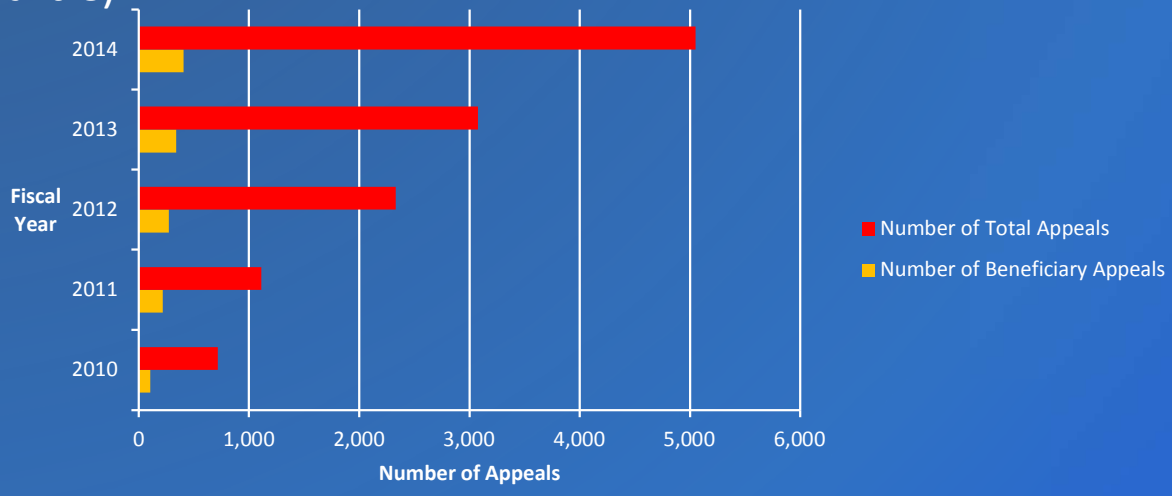
Number of Appeals Received by the Council Per Fiscal Year



**These numbers are based on OMHA workload predictions*

Beneficiary-Focus

- The Council is unlikely to meet the 90-day deadline for issuing decisions in most appeals
- The Council will give priority to beneficiary appeals (including Part C)



Review of Cases Escalated from OMHA

- The Council will:
  - NOT hold a hearing or conduct oral argument unless there is an extraordinary question of law/policy/fact
  - Only consider new evidence if the appellant has good cause for submitting it for the first time to the Council
  - Review the QIC's decision *de novo*
  - Take action within 180 calendar days beginning on the date the request for escalation is received by the Council
  - Issue a decision, dismissal, or remand to the ALJ for further proceedings

Office of Medicare Hearings and Appeals (OMHA)

This page contains information on:

- **Adjudication Timeframes**
- **Requests Submitted After April 1, 2013 — Deferred Assignment & Filing Alert for Requests and Additional Documentation**
- **Escalation Rights**
- **OMHA Medicare Appellant Forum**

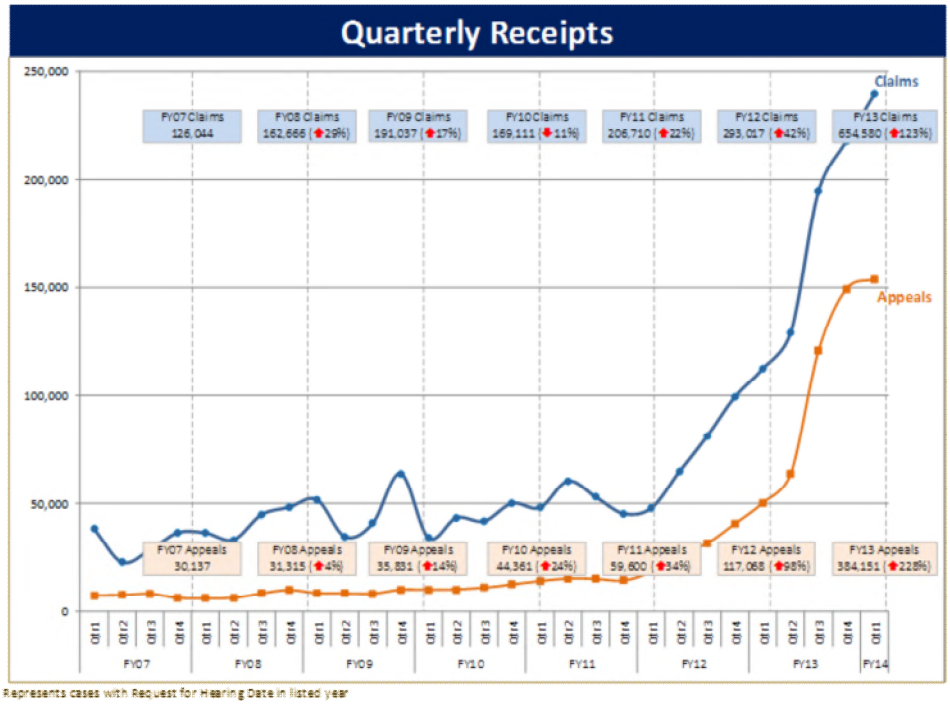
Adjudication Timeframes

Although OMHA is processing a record number of Medicare appeals, we continue to receive more requests for hearing than our Administrative Law Judges can adjudicate in a timely manner. OMHA remains committed to processing requests for hearing in the order received as quickly as possible given pending requests and adjudicatory resources. We will continue to process Part D prescription drug denial cases that qualify for expedited status within 10 days and will screen all incoming requests to ensure Medicare beneficiary issues are prioritized given that they often present emergent circumstances that must be promptly addressed. In all other circumstances, you (or your representative) will receive an Acknowledgement of Request letter when your request is docketed.

Due to record receipt levels, we are currently projecting an 20 - 24 week delay in entering ("docketing") new requests into our case processing system. If 22 weeks have not lapsed since you submitted your Request for Hearing, do not resubmit your request.

We are currently in the process of updating the expected adjudication times based on appeal receipt date. This will provide appellants with a more accurate timeline for their appeal.

The average processing time for appeals decided in fiscal year 2014 is 387 days.



Represents cases with Request for Hearing Date in listed year
Excludes reopened and combined appeals
FY14 receipts may be incomplete due to data entry backlog. Receipts complete as of January 2014.

Run Date: July 7, 2014

Decision Statistics

Appeals

FY12	FY13	FY14 (Data through June 2014)
Fully Favorable % 50.92%	Fully Favorable % 34.07%	Fully Favorable % 35.22%
Partially Favorable % 6.12%	Partially Favorable % 3.99%	Partially Favorable % 2.67%
Unfavorable % 26.65%	Unfavorable % 19.63%	Unfavorable % 28.57%
Remanded % 4.12%	Remanded % 23.00%	Remanded % 1.93%
Dismissed % 11.99%	Dismissed % 19.19%	Dismissed % 31.21%
Other % 0.20%	Other% 0.12%	Other% 0.40%

Claims

FY12	FY13	FY14 (Data through June 2014)
Fully Favorable % 30.66%	Fully Favorable % 29.45%	Fully Favorable % 26.92%
Partially Favorable % 14.85%	Partially Favorable % 9.68%	Partially Favorable % 9.67%
Unfavorable % 30.92%	Unfavorable % 23.98%	Unfavorable % 30.96%
Remanded % 7.09%	Remanded % 15.70%	Remanded % 1.67%
Dismissed % 14.29%	Dismissed % 20.72%	Dismissed % 29.94%
Other % 2.19%	Other% 0.47%	Other% 0.84%

Average Processing Time By Fiscal Year

Fiscal Year	Number of Days
FY09	94.9
FY10	109.6
FY11	121.3
FY12	134.5
FY13	220.7
FY14	
October	301.3
November	325.9
December	343.7
January	371.0
February	383.3
March	402.5
April	418.7
May	441.9
June	463.9
FY14 YTD Average	**387.2**

*Includes appeals decided in the listed fiscal year (does not include remands).
**Average days from Request for Hearing to Decision.
***Run Date: July 7, 2014

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Requests Submitted After April 1, 2013 — Deferred Assignment Filing Alert for Requests and Additional Documentation

Deferred Assignment

Due to the overwhelming number of receipts and the existing workload within the Agency, OMHA implemented a program that defers the assignment of most requests for hearing received after April 1, 2013. Under this new docketing process, new requests for hearing will be entered into our case processing system, then held until they can be accommodated on an Administrative Law Judge's docket for adjudication.

Due to the volume of requests that we are receiving, there are significant delays in assigning requests at this time. When your request is assigned to an Administrative Law Judge, we will send you a Notice of Assignment. Based on our current workload and volume of new requests, we anticipate that assignment of your request for hearing to an Administrative Law Judge may be delayed for up to 28 months.

Please note that we will continue to process Part D prescription drug denial cases that qualify for expedited status within 10 days and will screen all incoming requests to ensure Medicare beneficiary issues are prioritized given that they often present emergent circumstances that must be promptly addressed.

OMHA is now assigning a limited number of non-beneficiary appeals received between April and June 2013.

Filing Instructions Alert To OMHA Appellants

OMHA receives all previously submitted medical records and other documentary evidence from the Medicare contractor that conducted the decision that you are appealing (or from the Social security Administration, if it conducted the decision being appealed).

In order to manage the volume of appeals we are receiving, we ask that you please do the following:

- **Do not attach medical records or other documentary evidence to your request for Administrative Law Judge (ALJ) hearing**. Please limit your submission to the Request for ALJ hearing itself. See the "When to Submit Your Evidence" section below for instructions on how and when to submit additional evidence.
- **Clearly list the Medicare Appeal Number for the Reconsideration you are appealing on your Request for ALJ hearing form**. This number will appear in the upper right-hand corner of the reconsideration decision letter in the following format, e.g. 1-1234567890. Alternatively, please include a copy of the first page of your reconsideration decision.
- If you are appealing a reconsideration issued by a Qualified Independent Contractor (QIC), **DO NOT submit a courtesy copy of your request for ALJ hearing to the QIC that issued your reconsideration or to the Medicare Administrative Contractor (MAC) who issued your redetermination**. Neither the QIC nor the MAC require a copy for the purposes of 42 CFR § 405.1014(b)(2).

- **Do not re-submit medical records or other documentary evidence you already submitted earlier in the claim submission or to another level of appeal**.

  When you request an ALJ hearing, OMHA coordinates directly with the prior level of appeal to obtain the administrative record, **which includes everything you already submitted**. Duplicate evidence will not be considered.

When To Submit Additional Evidence or Briefs

- If you submit additional documentation (for example, additional evidence or briefs in support of coverage) to OMHA Central Operations **after you file your request**, but **before the case is assigned** to an ALJ, OMHA Central Operations will **return the materials to you**. OMHA Central Operations is devoting all resources to processing requests for hearing and cannot accommodate coordinating the additional materials at this time. You will have an opportunity to submit the additional materials after your case is assigned to an ALJ.

- When your request for hearing is assigned to an ALJ, we will send you a Notice of Assignment. This notice will reflect the name and address of the ALJ assigned to your case. If you would like to submit additional evidence related to your appeal, you should submit it after assignment directly to your assigned ALJ using the name and address referenced on this notice. Alternatively, you may submit your evidence directly to the ALJ within ten calendar days of receipt of the Notice of Hearing.

Special instruction for providers or suppliers: if you are submitting new evidence to the ALJ that was not previously submitted at any prior level of appeal, the evidence must be accompanied by a statement explaining why the evidence was not previously submitted. *See* 42 CFR § 405.1018. The ALJ will then examine any new evidence to determine whether there is good cause to submit the evidence for the first time at the ALJ level. 42 CFR § 405.1028.

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Escalation Rights

If you are appealing a Part A or Part B reconsideration issued by a Qualified Independent Contractor (QIC), you may have a right to escalate your request for hearing to the Medicare Appeals Council (MAC), 90 days after you file a complete request for hearing. More information on escalating a request for hearing can be found at 42 C.F.R. sections 405.1104 and 405.1106(b). When a request for hearing is escalated, the MAC may take any action in accordance with 42 C.F.R. section 405.1108(d), but is not required to conduct a hearing.

Escalating a request for hearing is a two-step process. See In re General Medicine, P.C. (MAC Sep. 6, 2007). To initiate the process, you must file a written request for escalation with OMHA. If your request has been assigned to an Administrative Law Judge, please file your request with the Administrative Law Judge's field office. Please clearly indicate your submission as an escalation request to help us process your request as quickly as possible. Our field office addresses can be found at http://www.hhs.gov/omha/contacts/offices.html.

If your request has not been assigned to an Administrative Law Judge, please file your request for escalation with:

OMHA — Central Operations
Attn: Escalation Request Mailstop
200 Public Square, Suite 1260
Cleveland, OH 44114

After OMHA receives your initial request for escalation, you may receive a decision, dismissal, remand order, or a Notice on Escalation Request. However, if you do not hear from us within 10 days (including 5 days for mailing time), you may consider your request escalated and proceed to seek MAC review of the escalated request. The request for MAC review must:

1. Contain the required content for a request for review of an escalated case set forth in 42 C.F.R. section 405.1112;

2. Be sent to both the MAC and the Administrative Law Judge's OMHA office (or OMHA Central Operations if you sent your request for escalation there); and

3. Be copied to the other parties to the appeal (for example, the parties who received a copy of the Notice of Reconsideration).

The address for the MAC is:

Department of Health and Human Services

Departmental Appeals Board, MS 6127

Medicare Appeals Council

330 Independence Ave., S.W.

Cohen Building, Room G-644

Washington, D.C. 20201

Please note that if you do not request MAC review of an escalated request, the case will remain pending with OMHA and the Administrative Law Judge adjudication process will continue.

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OMHA Medicare Appellant Forum

- **Letter from the Chief Administrative Law Judge**
- **OMHA Medicare Appellant Forum Brochure**
- **OMHA Medicare Appellant Forum Presentations**

Event Information

The Office of Medicare Hearings and Appeals (OMHA) held a Medicare Appellant Forum on February 12, 2014 to provide updates to OMHA appellants on the status of OMHA operations; relay information on a number of OMHA initiatives designed to mitigate a growing backlog in the processing of Medicare appeals at the OMHA-level of the administrative appeals process, and provide information on measures that appellants could take to make the administrative appeals process work more efficiently at the OMHA-level.

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Exploring the Impact of the RAC Program on Hospitals Nationwide

Results of AHA RAC*TRAC* Survey, 1st Quarter 2014

May 28, 2014

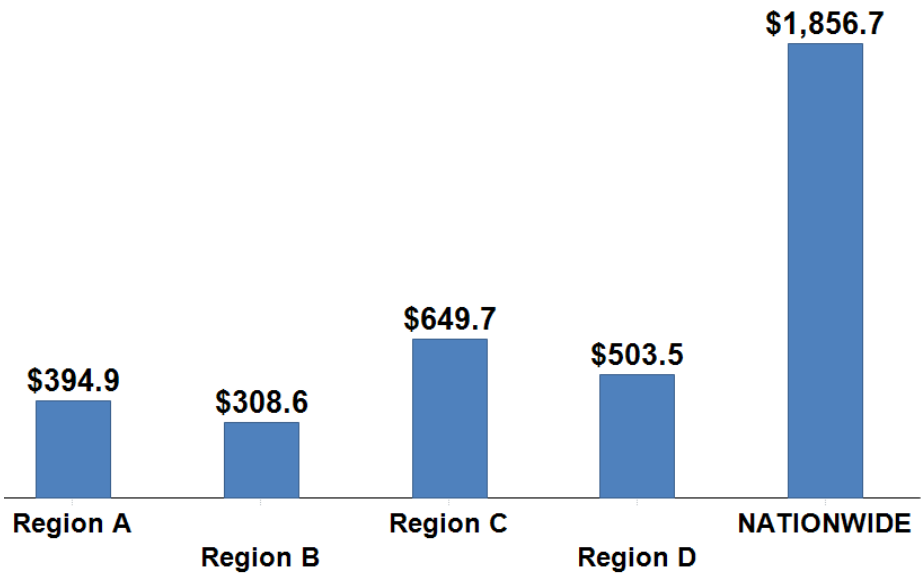
Executive Summary

- 2,489 hospitals have participated in RAC*TRAC* since data collection began in January of 2010. 1,165 hospitals participated this quarter.
- 57% of medical records reviewed by RACs **did not** contain an overpayment, according to the RAC.
- 59% of hospitals indicated they experienced short-stay medical necessity denials. 59% of hospitals also received denials for inpatient coding, an increase of 8% from Q4 2013.
- 66% of short-stay denials for medical necessity were because the care was provided in the wrong setting, not because the care was medically unnecessary
- Hospitals reported appealing 50% of all RAC denials, with a 66% success rate in the appeals process.
  - The appeals overturn rate may be impacted by appeals withdrawn by hospitals for rebilling. An additional 13,000 claims were reported as withdrawn from the appeals process by hospitals since Q3 2013.

The value of appealed claims exceeds $1.8 billion dollars. Hospitals report appealing an average of 386 claims to date.

Total Dollar Value, Percent and Average Number of Appealed Claims for Hospitals with Automated or Complex RAC Denials, through 1st Quarter 2014, Millions

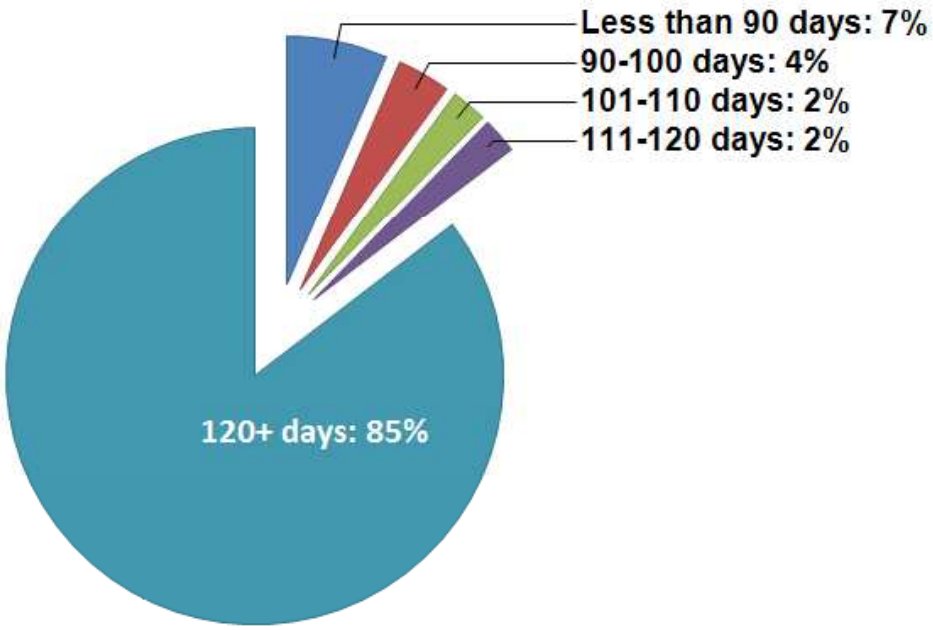
	Percent of Hospitals with Any Appealed Denials	Average Number of Appealed Denials per Hospital
NATIONWIDE	89%	386
Region A	89%	390
Region B	89%	279
Region C	91%	388
Region D	84%	502



Source: AHA. (April 2014). RAC*TRAC* Survey
AHA analysis of survey data collected from 2,489 hospitals: 2,221 reporting activity, 268 reporting no activity through March 2014. 1,165 hospitals participated this quarter. Data were collected from general medical/surgical acute care hospitals (including critical access hospitals and cancer hospitals), long-term acute care hospitals, inpatient rehabilitation hospitals and inpatient psychiatric hospitals.

93% of reporting hospitals have experienced at least one delay longer than the statutory limit of 90 days for an ALJ determination to be issued.

Percentage of Reporting Hospitals by Longest Delay Experienced for ALJ to Issue a Decision on an Appeal, for Participating Hospitals, 1st Quarter 2014



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Of the claims that have completed the appeals process, 66% were overturned in favor of the provider.

Summary of Appeal Rate and Determinations in Favor of the Provider, for Hospitals with Automated or Complex RAC Denials, through 1st Quarter 2014*

				Completed Appeals		
	Appealed	**Percent of Denials Appealed**	**Number of Denials Awaiting Appeals Determination**	**Number of Denials Not Overturned from Appeals Process**** (Withdrawn/Not Continued)	**Number of Denials Overturned in the Appeals Process**	**Percent of Appealed Denials Overturned** *(as a Percent of Total Completed Appeals)*
NATIONWIDE	267,085	52%	171,967	29,621	58,748	66%
Region A *	17,833	53%	10,418	3,393	3,135	48%
Region B	52,717	49%	29,427	7,938	13,372	63%
Region C	118,720	50%	81,458	10,338	25,043	71%
Region D	77,815	56%	50,664	7,952	17,198	68%

**Manual survey entries only for Region A. Due to survey submission error, total appeals may be greater than the sum of ending/withdrawn/overturned appeals.*
*** May include appeals withdrawn to re-bill.*

*Response rates vary by quarter.

Source: AHA. (April 2014). RAC*TRAC* Survey
AHA analysis of survey data collected from 2,489 hospitals: 2,221 reporting activity, 268 reporting no activity through March 2014. 1,165 hospitals participated this quarter. Data were collected from general medical/surgical acute care hospitals (including critical access hospitals and cancer hospitals), long-term acute care hospitals, inpatient rehabilitation hospitals and inpatient psychiatric hospitals.

InsideHealthPolicy
An Inside Washington news service

INSIDE CMS - 02/20/2014

ALJs Lay Path Forward For Stakeholders As Appeals Backlog Continues

Posted: February 20, 2014

Providers, beneficiary advocates, contractors and other stakeholders this week gathered to hear what the Office of Medicare Hearings and Appeals has in the works to relieve the backlog of claims clogging the third level of the Medicare appeals system, and they were told, while there is no silver bullet, several initiatives are underway. OMHA outlined planned projects and improvements to help increase the Administrative Law Judges' efficiency while also acknowledging the burden the situation has placed on those waiting for appeals to be heard.

The office said it will formally seek stakeholders' advice on ways to handle the backlog and suggested one option is for those appealing to waive their right to a hearing to quicken the process. The office also revealed plans to prioritize beneficiary claims, hire more people, open a Central Time Zone office, explore alternate adjudication models including a pilot letting attorneys fast-track claims reviews, launch a slew of information technology initiatives, and write a manual injecting a degree of consistency across ALJs.

Chief Administrative Law Judge Nancy Griswold told stakeholders at the OMHA forum Wednesday (Feb. 13) that the wait times before providers and beneficiaries can get a Medicare appeal at the third level are unacceptable. The agency knows this, she said, and is committed to making changes -- but she added there is no silver bullet to solving the problems created by the ever-growing backlog of appeals. OMHA received more than 15,000 appeals per week as of January, Griswold said, and given those levels of appeals there is no one approach that will quickly provide a solution to the problem.

A letter from Griswold sent to those appealing claims in December says that because of "rapid and overwhelming increase in claim appeals, effective July 15, 2013, OMHA temporarily suspended the assignment of most new requests for an Administrative Law Judge hearing to allow OMHA to adjudicate appeals" already waiting in the backlog. OMHA also announced plans to hold a public forum.

The chief ALJ said that, as of January, those appealing claims were looking at a 28-month wait before appeals are assigned to an Administrative Law Judge, and OMHA has also noted a six-month wait after assignment before those appealing can expect a hearing. One ALJ suggested that cases might be handled quicker if those appealing waive their right to a hearing and put forth all of their arguments and evidence in writing, though he noted that is not always the best option.

A limited number of claims were starting to be assigned to ALJs as of Feb. 3, Griswold said. She also emphasized that beneficiary claims will be considered priority cases.

Notice seeking comment. OMHA plans to publish a notice asking stakeholders for their comments and suggestions on how to handle the backlog, Griswold said. Some, including the American Hospital Association, have already put forward suggestions.

New office and more resources. OMHA is also planning to open a Central Time Zone office, and Griswold told stakeholders that the agency has seen an 18.6 percent increase to its budget over last year. OMHA is looking to bring additional resources on board, Griswold said, but it will take time to hire and train more staff.

Alternative adjudication models. Jason Green, the director of the program evaluation and policy division at OMHA, said the agency is looking to "alternate adjudication models" to help handle the backlog, and Griswold said the agency is looking at greater group appeals, mediation, alternative dispute resolution and, if those appealing agree, statistical sampling.

Green said alternative options could provide more tools for reaching a resolution. The agency is also looking at using pilots to test alternative appeals models and demonstrate they are viable, Green said.

OMHA attorney case review pilot. One pilot under consideration would allow for OMHA attorney case reviews. Such a program could "fast track" claims that look like they may favor the person appealing or narrow issues for a hearing. If allowing the attorneys to review and settle appeals works, Green said OMHA would pursue regulations to allow for such a program outside of a pilot. While Green acknowledged this would be a longer-term solution, he said it is something to start looking at, and it could bring more efficiency to the process.

OMHA also has a slew of IT initiatives planned that as part of the solution.

A spokesperson for American Coalition for Healthcare Claims Integrity, which represents Recovery Audit Contractors, said the group would be open to the idea of alternatives, and would support efforts to speed up the appeals process -- provided the alternatives still followed Medicare policy. But the group would need more details before backing any specific appeals alternatives.

ALJ manual. Griswold and Green also said OMHA is working on a manual for ALJs, with a goal to create more consistency across the ALJs. Consistency among the ALJs has been a concern for the Office of Inspector General, which pointed out that the number of denials overturned varied greatly between the different judges.

The American Coalition for Healthcare Claims Integrity said that their central concern is the inconsistency of ALJ reviews and decisions. "While we welcome many of the proposals presented by OMHA officials to address this issue, such as the adjudication manual and ALJ educational symposia, we will continue to push OMHA to impose strict Medicare compliance requirements on the ALJ," the coalition said in a statement.

One stakeholder asked if the manual would be available for public comment. Griswold said the manual will be looking at uniformity, case process, and best practices, and as it will address internal practices, she had not envisioned having a public comment on the manual.

Griswold also noted that if you look at any judicial process, there will be some differences in the way judges decide cases. As long as the judges are with the framework of Medicare policy, the ALJs have the authority to apply the Medicare policy in the way their conscience dictates within the law.

Stakeholders at the forum noted the lack of consistency between decisions at the ALJ level and those at the first two levels of the appeals system, and some said the feedback loops between the different levels of appeals need to be tightened. One stakeholder questioned this inconsistency between the different levels of appeals, and as the ALJs are bound to Medicare policy, wondered if it would be fair to say that Medicare law had not been correctly applied in cases where denials were overturned by the ALJs.

Griswold said that while the ALJs are adhering to Medicare policy, the judges may reach a different conclusion than the lower appeals levels as they get to hear those appealing the case, and may see additional evidence, testimony and explanation during the hearing process.

Holistic approach. One of the silver linings to the clogged appeals process is that all levels of the appeals process are beginning to look at the appeals work holistically, Griswold said. Board Chair of the Medicare Appeals Council Constance B. Tobias noted that the council's workload is directly related to what OMHA processes, and noted that appeals at the fourth level have also increased. With the number of appeals the council is seeing, it is also unlikely to meet its 90-day deadline for deciding appeals, she added.

Green said that although many of the tools OMHA is considering will increase efficiency, the agency cannot address the cases only in terms of moving them faster through the process. There also needs to be a focus on quality, Green said.

One stakeholder suggested that OMHA should be trying to find ways to reduce the number of cases filed rather than focusing simply on how to process them quickly. Another said that the fact that the lower levels of the appeals system don't seem to be working is a systemic problem, and if that root problem is addressed some of the issues at the higher appeals levels will be resolved. -- *Michelle M. Stein*

72348

STATEMENT OF

NANCY J. GRISWOLD

CHIEF ADMINISTRATIVE LAW JUDGE

OFFICE OF MEDICARE HEARINGS AND APPEALS

ON

"OFFICE OF MEDICARE HEARINGS AND APPEALS WORKLOADS"

BEFORE THE

UNITED STATES HOUSE COMMITTEE ON OVERSIGHT & GOVERNMENT REFORM

SUBCOMMITTEE ON ENERGY POLICY, HEALTH CARE & ENTITLEMENTS

JULY 10, 2014

U.S. House Committee on Oversight & Government Reform

Subcommittee on Energy, Health Care & Entitlements

Hearing on Office of Medicare Hearings and Appeals Workloads

July 10, 2014

Chairman Lankford, Ranking Member Speier and members of the Subcommittee, thank you for the invitation to discuss the workloads at the Office of Medicare Hearings and Appeals (OMHA). OMHA, a staff division within the Office of the Secretary of the U.S. Department of Health and Human Services (HHS), administers the nationwide Administrative Law Judge hearing program for Medicare claims and entitlement appeals under sections 1869 and 1155, of the Social Security Act (the Act). OMHA ensures that Medicare beneficiaries, and the providers and suppliers that furnish items or services to Medicare beneficiaries, as well as Medicaid State Agencies, have a fair and impartial forum to address disagreements with Medicare claim determinations. This includes determinations related to Medicare eligibility and entitlement, as well as income-related premium surcharges made by the Social Security Administration (SSA). In addition, OMHA provides hearings on appeals of coverage determinations made by Medicare Advantage Organizations, health maintenance organizations, competitive medical plans, and Part D plan sponsors under sections 1876(c)(5)(B), 1852(g)(5), and 1860D-4(h) of the Act.

The Medicare claims appeals process consists of four levels of administrative review within HHS, and a fifth level of review with the federal district courts after administrative remedies within HHS have been exhausted. The first two levels of review are administered by the Centers for Medicare & Medicaid Services (CMS) and conducted by Medicare contractors. The third level of review is administered by OMHA and is conducted by Administrative Law Judges. Subsequent reviews are conducted at the fourth level of appeal within the Departmental Appeals Board (DAB), and at the fifth level by the federal district courts.

The Medicare entitlement appeals process consists of three levels of administrative review, and a fourth level of review with the federal district courts after administrative remedies have been exhausted. The first level is the reconsideration level conducted by the SSA. The second level of review is administered by OMHA and is conducted by Administrative Law Judges. Subsequent reviews are conducted at the third level of appeal within the DAB and at the fourth level by the federal district courts.

The Department established OMHA in June, 2005, pursuant to section 931 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173) (MMA) which required the transfer of responsibility for the Administrative Law Judge hearing

function of the Medicare claims and entitlement appeals process from the SSA to the Department of Health and Human Services. OMHA was established to improve service to appellants and to reduce the average 368-day waiting time for a hearing decision that appellants experienced with SSA to the 90-day time frame for issuing dispositions established in the Medicare, Medicaid, and SCHIP Benefits and Improvement Act of 2000 (BIPA) (Pub. L. 106-554). In order to ensure that OMHA's adjudicators would have decisional independence from CMS, OMHA was established as a separate agency within the Department of Health and Human Services, reporting directly to the Secretary. Accordingly, OMHA operates under a separate appropriation and is both functionally and fiscally separate from CMS.

At the time OMHA was established, Congress envisioned that OMHA would receive:

- Claim and entitlement appeals workload from the Medicare Part A and Part B programs:
- Coverage appeals from the Medicare Advantage (Part C) program;
- A new workload of appeals from the Medicare Prescription Drug (Part D) program; and
- Appeals of Income Related Monthly Adjustment Amount (IRMAA) premium surcharges assessed by SSA.

With this mix of work at the expected levels, OMHA was for the most part able to meet the 90-day time frame that Congress contemplated for most appeals. However, starting in FY 2010, OMHA began to experience an upward trend in the number of requests for hearings and delays in the average processing times for appeals.

From FY 2011 thru FY 2013, the upward trend in receipt levels took an unexpectedly sharp turn and OMHA experienced an overall 545% growth in appeals (from 59,600 in FY 2011 to 384,151 in FY 2013). This rise in the number of appeals resulted both from increases in the number of beneficiaries utilizing services covered by Medicare (CMS now processes more than one billion claims annually) and from the expansion of OMHA's responsibility to adjudicate appeals resulting from new audit workloads, including the nationwide implementation of the Recovery Audit Program in 2010. The Recovery Audit Program, established by Congress, has been very successful, returning billions in improper payments to the Medicare Trust Fund. Only 7% (99,492) of the 1.419 million Recovery Auditors claims identified as overpayments were challenged and overturned on appeal as published in the Centers for Medicare and Medicaid Services (CMS) FY 2012 Report to Congress. There have also been increases in Medicaid State Agency (MSA) appeals of Medicare coverage denials for beneficiaries enrolled in both Medicaid and Medicare. Although ALJ team productivity (dispositions per ALJ) more than doubled from FY 2009 through FY 2013 (from an average of 534 dispositions per ALJ team per year in FY 2009 to 1260 in FY 2013), the magnitude of these increases in workload has exceeded OMHA's ability to adjudicate incoming appeals within the 90-day time frame that Congress contemplated for most appeals. As a result of the significant disparity between workload and capacity, adjudication time frames have increased to their current level of 387 days (as of June 30, 2014).

OMHA has been able to maximize its productivity by supporting each of its ALJs with assigned processing teams consisting of attorneys and other support staff. This has allowed

each ALJ to focus on hearing and deciding appeals—functions which can only be performed by ALJs. However, OMHA's adjudication capacity is still limited by the number of ALJ teams on board. Under the 2014 continuing resolution, OMHA's funding level supported 65 ALJ teams. OMHA's 2014 enacted funding level allowed for the hiring of 7 additional teams, who will report on August 25, 2014. This will bring OMHA's adjudication capacity to approximately 72,000 appeals per year. However, this capacity pales in comparison to the adjudication workload. In FY 2013 alone, OMHA received 384,151 appeals, and in FY 2014 receipt levels through July 1 are approximately 509,124 appeals. Weekly appeal levels have ranged between 10,000 and 16,000 throughout FY 2014. As a result, OMHA had over 800,000 appeals pending on July 1, 2014. At current receipt and adjudication capacity levels, OMHA's Central Operations, which is the focal point for all incoming appeals, is receiving one year's worth of appeals every four to six weeks.

Due to the rapid and persistent influx of appeals, OMHA's four field offices faced significant challenges in their ability to safely store the high number of files pending hearing. As a consequence, OMHA began deferring its requests for case files from the lower appeal levels, and deferred the assignment of most requests for hearing to an Administrative Law Judge (ALJ), until they could be accommodated on an ALJ's docket. The decision to defer assignment of appeals was a management decision related to the geography of case storage and did not cause any additional delays in the hearing and decision of appeals. Although the assignment of most appeals has been deferred under this process, appeals filed by beneficiaries, our most vulnerable appellants, comprise less than 2% of our workload and continue to be given priority assignment to ALJs. In February, 2014, OMHA began to assign a limited number of non-beneficiary appeals to judges who were able to accommodate additional appeals on their dockets. Throughout this time, OMHA has continued to conduct hearings and issue decisions on appeals already assigned.

Recognizing the impact the growing workload would have on our appellant community and the need for transparency with regard to its growing workloads, OMHA held an Appellant Forum on February 12, 2014, to inform stakeholders of its operating status. Over 800 individuals attended the forum either in person or by webinar. In addition to presentations by OMHA, both CMS and the DAB presented information concerning their workloads and processes. OMHA's next Appellant Forum is tentatively scheduled for October 29, 2014, and will be formally announced on our website in the near future.

In the face of dramatically increasing workloads, OMHA recognizes the need to deliver high quality and timely decisions on benefits and services to the Medicare community with greater efficiency. By the end of the fiscal year we will release our adjudicative business process manual, which will utilize best practices to standardize our business processes. We are using information technology to convert our process from paper to electronic. This effort will culminate in the first release of our Electronic Case Adjudication Processing Environment (ECAPE) in the summer of 2015. We have also developed a Medicare Appeals Template System (MATS), which simplifies the work of our staff by providing standardized fillable formats for routine word processing.

Recognizing the gravity of its workload challenges, OMHA proposed and former Secretary Sebelius established a departmental interagency workgroup in 2013, which included leaders from each of the three agencies involved in the Medicare appeals process (CMS, OMHA, and DAB). This interagency group conducted a thorough review of the appeals process and developed a series of initiatives that both OMHA and CMS are implementing to reduce the current backlog of pending appeals and the number of appeals that reach OMHA.

As a result of this cross-component cooperation and the assistance we have received from departmental leaders, OMHA is now implementing a number of pilot programs. On June 30, OMHA posted on its website two new options for appellants seeking resolution of their appeals. The first allows appellants to have their claims adjudicated using statistical sampling and extrapolation. This initiative facilitates resolution of large numbers of claims based upon resolution of a statistically valid sample. The second new option for appellants uses alternative dispute resolution techniques during a facilitated settlement conference conducted by OMHA attorneys who have been trained in mediation techniques. OMHA will be monitoring the performance of these pilots and, if successful, will roll them out nationally as funding allows. Finally, to bolster the processing of beneficiary appeals as our first priority, OMHA has redirected the efforts of its senior attorneys to assist in the prioritization of these appeals. Any beneficiary who believes their case is not receiving priority consideration at OMHA may contact us directly by e-mail at Medicare.Appeals@hhs.gov or at OMHA's toll free number, 855-556-8475.

OMHA is, by Congressional design, functionally and organizationally separate from CMS and its review processes. I understand, however, that in addition to the initiatives OMHA has undertaken to mitigate workload challenges, CMS also has taken a number of steps intended to substantially reduce the number of appeals submitted to OMHA. While CMS would be in the best position to address the specifics of those initiatives, I can provide a general outline. These initiatives include: a) beginning global settlement discussions involving similarly-situated claimants; b) under the new fee for service recovery audit contracts, requiring the new Recovery Auditors to offer providers and suppliers a 30-day discussion period to allow an opportunity for resolution before the Recovery Auditor refers a claim to the Medicare Administrative Contractor for collection; c) under the new fee for service recovery audit contracts, allowing for payment only after CMS' Qualified Independent Contractor (QIC) has made a determination supporting the recovery auditor's determination of an overpayment; d) issuing a proposed rule requiring prior authorization for certain durable medical equipment frequently subject to overutilization; and e) using CMS's demonstration authority to require prior authorization for two particular Part B services.

OMHA is privileged to have an extremely dedicated workforce of both Administrative Law Judges and staff who remain committed to processing Medicare appeals in both a quality and timely fashion. While the Department is working to address the backlog and the number of prospective appeals with current resources and authorities, the initiatives discussed today are

insufficient to close the gap between workload and resources at OMHA. Although all workloads at OMHA have experienced rapid growth, a significant portion of the increase is a consequence of the Department's efforts to implement legislation designed to combat Medicare fraud and reduce improper payments. The Department is committed to bringing these efforts and the resulting appeal workload into balance. With that goal in mind OMHA continues to work with departmental leaders to develop comprehensive solutions to its growing workloads and we also look forward to working with this committee and our stakeholders to develop and implement these solutions.

Office of Medicare Hearings and Appeals (OMHA)

U.S. Department of Health and Human Services

Nancy J. Griswold

Chief Administrative Law Judge for the Office of Medicare Hearings and Appeals (OMHA)

Judge Nancy Griswold was appointed Chief Administrative Law Judge for the Office of Medicare Hearings and Appeals on March 1, 2010. In this capacity, she oversees the third level review for Medicare appeals within the U.S. Department of Health and Human Services and has responsibility for the second largest Administrative Law Judge (ALJ) corps in the federal system. Chief Judge Griswold brings with her a wealth of administrative and managerial experience beginning over two decades ago.

Chief Judge Griswold graduated from Baylor University Law School then entered private practice as a labor lawyer in Dallas, Texas. She then moved to Shreveport, Louisiana where her general civil practice centered on personal injury, products liability and aircraft accident trial litigation. In 1990, she left private practice to assist in the development of the Louisiana's worker's compensation administrative court system. Judge Griswold became the first Chief Judge of the Louisiana Workers Compensation Court, a post she held for three years. During her tenure, Judge Griswold established and staffed the Office of the Chief Judge and created a Workers' Compensation Mediation Program for the State of Louisiana.

Since her appointment as a federal Administrative Law Judge in 1995, Chief Judge Griswold has held progressively more responsible positions within the federal government. She began her federal career as an Administrative Law Judge in the Shreveport, Louisiana, Social Security Office of Hearings and Appeals in June of 1995. At the time of her appointment she was one of the youngest judges ever appointed as a Federal Administrative Law Judge. In January, 2002,

she became the Hearing Office Chief Administrative Law Judge in Shreveport, Louisiana, where she continued to serve until her appointment as acting and then permanent Regional Chief Judge for the Boston Region in July of 2004. As Regional Chief Administrative Law Judge in Boston, Judge Griswold was the national lead for implementation of the Commissioner's Disability Service Improvement initiative at the hearings level. In this capacity, she oversaw the formulation of training, development of requirements for computer enhancements, and formulation of procedural rules and templates for the hearing operation. She also worked on the Medicare transition team, which developed recommendations for the smooth transition of the Medicare workload to the Office of Medicare Hearings and Appeals in July, 2005. Judge Griswold continued to serve in Boston until her appointment as Deputy Chief Administrative Law Judge for the Social Security Administration in December, 2006.

In her capacity as Deputy Chief, Judge Griswold served as alter ego for the Chief Administrative Law Judge and worked closely with him on the formulation of Social Security's extremely successful backlog elimination plan. During her tenure as Deputy Chief Administrative Law Judge, the Social Security Administration reached new levels of productivity and prior to her departure had driven the backlog down for 14 successive months. She also had oversight of the Administrative Law Judge hiring program at Social Security and recommended over 300 Administrative Law Judges for appointment during her tenure. In her capacity as Deputy Chief, Judge Griswold served as subject matter expert during the design and implementation of five new state of the art video conferencing offices called the National Hearing Centers for Social Security's Office of Disability Adjudication and Review—based in large part upon the Office of Medicare Hearings and Appeals adjudication model for video teleconferencing hearing procedures. As Deputy Chief Administrative Law Judge for Social Security, she assisted the Chief Judge in the management of over 8000 employees, including 1200 Administrative Law Judges and 142 hearing offices.

Chief Judge Griswold is a member of the Texas, Louisiana and Colorado State Bar Associations.

February 12, 2014

Nancy J. Griswold
Chief Administrative Law Judge
Office of Medicare Hearings and Appeals
Department of Health & Human Services
1700 N. Moore Street
Suite 1800
Arlington, VA 22209

Dear Chief Administrative Law Judge Griswold:

On behalf of the undersigned organizations, we write to you to express serious concern about the backlog of Medicare appeals. We are particularly troubled by the recent notice by the Office of Medicare Hearings and Appeals (OMHA) that assignment of requests for Administrative Law Judge (ALJ) hearings may be delayed for up to 28 months. We are also discouraged that OMHA still predicts that, even after this delay, post-assignment hearing wait times are likely to continue to exceed six months. While we understand and appreciate that OMHA has convened a forum today to discuss the backlog of Medicare appeals, we are concerned that this forum alone will not sufficiently address the multitude of issues that patients and physicians face when the Medicare appeals process is not working properly. **We therefore strongly urge OMHA to develop a comprehensive solution to the Medicare appeal backlog problem so that appealed cases may be assigned and adjudicated without delay.**

As you are aware, Medicare audit contractors are often erroneous in their overpayment determinations. In particular, the Recovery Auditors, or RACs, have a very poor accuracy record. The most recent Centers for Medicare & Medicaid Services (CMS) RAC report to Congress stated that 43.6 percent of provider-appealed RAC determinations are overturned. Because the Medicare contractors often get it wrong, the Medicare appeals process is of utmost importance. A physician who undergoes a RAC audit and believes that the RAC has erroneously recouped a payment has but one recourse: they may file an appeal of the RAC determination through the Medicare appeals process. Many of these cases proceed all the way to the ALJ level and are overturned. By delaying the *assignment* of cases to ALJs by more than two years, OMHA is denying due process which is predicated on the timely disposition of disputes for physicians and other providers who experience erroneous determinations by Medicare contractors.

The proposal to further delay processing appeals is the most recent example of the barriers to obtaining payment for the delivery of medically necessary and reasonable services to Medicare beneficiaries. Over the course of years, physicians have increasingly assumed the cost of producing medical records (often repeatedly at various levels of appeal), meeting exacting deadlines, and filing a succession of appeals. The foregoing does not capture the additional opportunity cost associated with the diversion of physician and staff hours from delivering direct medical care to patients. The OMHA appeals process is but one appeals process that physicians and patients must navigate. We recommend that OMHA and the Office

of the Secretary within the U.S. Department of Health & Human Services (HHS) evaluate the need for expedient appeals processes across the health programs administered by HHS, including Medicare, Medicare Advantage, and the Medicare Prescription Drug benefit. The numerous appeals requirements, actual costs of filing appeals, and often lengthy delays undermine the ability of physicians to deliver patient-centered care.

As a necessary first step, we strongly urge you to remedy the OMHA backlog immediately. With the numerous new regulatory requirements that physicians are facing today, physicians do not have the resources to navigate an interminable appeals process. We are happy to work with you as you address these issues.

Sincerely,

American Medical Association
American Academy of Allergy, Asthma & Immunology
American Academy of Dermatology Association
American Academy of Family Physicians
American Academy of Home Care Medicine
American Academy of Ophthalmology
American Academy of Otolaryngic Allergy
American Academy of Otolaryngology—Head and Neck Surgery
American Association for Geriatric Psychiatry
American Association of Clinical Endocrinologists
American Association of Neurological Surgeons
American College of Allergy, Asthma and Immunology
American College of Cardiology
American College of Emergency Physicians
American College of Gastroenterology
American College of Mohs Surgery
American College of Physicians
American College of Phlebology
American College of Rheumatology
American College of Surgeons
American Congress of Obstetricians and Gynecologists
American Osteopathic Association
American Psychiatric Association
American Society for Clinical Pathology
American Society for Gastrointestinal Endoscopy
American Society for Surgery of the Hand
American Society of Cataract and Refractive Surgery
American Society of Clinical Oncology
American Society of Dermatopathology
American Society of Hematology

American Society of Neuroradiology
American Society of Ophthalmic Administrators
American Society of Retina Specialists
American Thoracic Society
American Urological Association
College of American Pathologists
Congress of Neurological Surgeons
Heart Rhythm Society
International Spine Intervention Society
Joint Council of Allergy, Asthma and Immunology
Medical Group Management Association
North American Spine Society
Renal Physicians Association
Society for Cardiovascular Angiography and Interventions
Society for Vascular Surgery
Society of Hospital Medicine
The Society of Thoracic Surgeons

Medical Association of the State of Alabama
Alaska State Medical Association
Arkansas Medical Society
Arizona Medical Association
California Medical Association
Colorado Medical Society
Connecticut State Medical Society
Medical Society of Delaware
Medical Society of the District of Columbia
Florida Medical Association Inc
Medical Association of Georgia
Hawaii Medical Association
Idaho Medical Association
Illinois State Medical Society
Indiana State Medical Association
Iowa Medical Society
Kansas Medical Society
Kentucky Medical Association
Louisiana State Medical Society
Maine Medical Association
MedChi, The Maryland State Medical Society
Massachusetts Medical Society
Michigan State Medical Society
Minnesota Medical Association
Mississippi State Medical Association

Missouri State Medical Association
Montana Medical Association
Nebraska Medical Association
Nevada State Medical Association
New Hampshire Medical Society
Medical Society of New Jersey
New Mexico Medical Society
Medical Society of the State of New York
North Carolina Medical Society
North Dakota Medical Association
Ohio State Medical Association
Oklahoma State Medical Association
Oregon Medical Association
Pennsylvania Medical Society
Rhode Island Medical Society
South Carolina Medical Association
South Dakota State Medical Association
Tennessee Medical Association
Texas Medical Association
Utah Medical Association
Vermont Medical Society
Medical Society of Virginia
Washington State Medical Association
West Virginia State Medical Association
Wisconsin Medical Society
Wyoming Medical Society

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AdvaMed
Advanced Medical Technology Association

March 27, 2014

Kathleen Sebelius
U.S. Department of Health and Human Services
200 Independence Ave., SW
Washington, DC 20201

Marilyn Tavenner, Administrator
Centers for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244-1813

Re: Office of Medicare Hearings and Appeals (OMHA) Decision to Suspend Assignment of New Requests for Administrative Law Judge (ALJ) Hearings for Adjudication of Appeals

Dear Secretary Sebelius and Administrator Tavenner,

The Advanced Medical Technology Association (AdvaMed) is writing regarding the Office of Medicare Hearings and Appeals' (OMHA) recent policy decision to suspend for two years the assignment of new requests for Administrative Law Judge (ALJ) hearings for adjudication of appeals. AdvaMed member companies produce the medical devices and diagnostic products used by many Medicare providers who will be adversely impacted by this policy. We oppose OMHA's decision and are very concerned that the policy will create significant harm for both patients and providers. Given our concerns, we request that (1) the Department of Health and Human Services (HHS) and Centers for Medicare & Medicaid Services (CMS) take immediate action to relieve the current Medicare appeals backlog and the financial strain OMHA's decision places on providers, and (2) CMS work with OMHA to develop and put in place long-term improvements to the Medicare audit and appeals processes.

I. The current backlog and OMHA's decision contradict both the language and the intent of the Social Security Act, and results in significant financial strain on providers, suppliers, and patients

The Medicare appeals process was established to provide Medicare beneficiaries with the opportunity to appeal a Medicare decision without resorting to the courts.[1] Section 1869 of the Social Security Act (SSA), added by the Beneficiary Improvement and Protection Act, establishes deadlines for the review of Medicare appeals at all levels.[2] Where the reviewing body misses a statutory deadline, the appellant is permitted to proceed to the next level of appeal. ALJ hearings must be adjudicated within 90 days under section 1869(d)(1) of the Act. OMHA's decision to ignore these requirements so that no new requests for ALJ hearings would exceed the 90-day statutory deadline, even if the suspended status takes years, plainly violates the statute and contradicts the purpose of the Medicare appeals process.

The current backlog across the review levels for appeals cannot be reconciled with the goals of the statutory scheme for Medicare appeals. If a hospital were to appeal a Medicare Part A coverage decision and then exercise its right to proceed to the higher level of review at the end of each missed deadline at each level of review, the case is virtually certain to end up in queue for a review by a federal court without having been reviewed by an ALJ or the Medicare Appeals Council, and likely without having been reviewed by a Qualified Independent Contractor (QIC). The result would be the absence of an administrative record when the appeal reached the federal courts, leading to precisely the result that the Supreme Court warned about in *Heckler v. Ringer* and that the enactment of section 1869 was designed to prevent. In practice, the current backlog renders the statutory deadlines irrelevant, thus contradicting the statutory mandate. OMHA's decision to suspend the assignment of requests for ALJ hearings only perpetuates the backlog that eliminates the statutory schedule of appeal reviews. OMHA failed to offer any legal authority that permits OMHA to defer the assignment of timely filed ALJ appeals.

In addition to contradicting the mandate of the SSA, OMHA's decision undermines the financial stability of Medicare providers, who have already seen significant revenues tied up in pending appeals as the backlog for ALJ adjudication has grown. Stated simply, the accumulation of appealed claims at OMHA leads to the accumulation of providers' funds at CMS and is unfair to providers who are partners with Medicare in ensuring beneficiaries access to the care they need.

AdvaMed therefore opposes OMHA's proposed stop-gap measure, and offers several suggestions for the resolution of the backlog and the long-term improvement in the efficiency of review. In the short term, HHS should find additional funding for OMHA's budget, beyond the increase established for FY 2014, to provide the resources OMHA needs to adjudicate appeals in

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[1] *See Heckler v. Ringer*, 466 U.S. 602, 627 (1984) (holding that Congress did not intend a process whereby there could be "premature judicial intervention in an administrative system that processes literally millions of claims every year.").

[2] Pub. L. No. 106-554 § 522, 114 Stat. 2763A-1, 543 – 47 (Dec. 21, 2000).

the timeframe required by law. As we recommend below, additional funding would become available if CMS were to put in place a temporary moratorium on audits until much of the backlog of pending appeals requests was eliminated. HHS should also implement long term solutions, including separating appeals by categories, establishing default judgments for providers in some cases, and establishing a clinical inference review in the redetermination and reconsideration levels.

II. CMS should take immediate action to relieve the appeals backlog

CMS can take a number of interim steps to reduce the financial strain faced by providers as a result of a large backlog of appeals requests and OMHA's decision to suspend the assignment of new requests for ALJ hearings:

- CMS should impose a ***moratorium of all pre- and post-payment audits of claims until the backlog is reduced*** to not more than six months. The increase in appeals cases is driven largely by the expansion of post-payment audits, specifically, Recovery Audit Contractor (RAC) and Zone Program Integrity Contractor (ZPIC) audits.[3] Pausing all audits until improvements are made to the Medicare appeals system would allow OMHA to reduce the backlog by preventing the flood of the anticipated new appeals. At the very least, CMS should impose a moratorium on complex medical reviews that have higher rates of appeal. It is a legitimate agency response that would bring balance and sanity to the current situation.

- HHS should use its budgetary authority to ***redirect funding that would be available from the temporary suspension of new audits to OMHA for the hiring of additional resources to reduce the backlog of appeals requests***.

- ***Providers should be excluded from pre- and post-payment audits for one-year if they have a low payment error rate***. This measure would allow CMS to target its audits more efficiently.

- With the significant delay in adjudication of appeals, ***CMS should not recoup disputed funds until after the provider has received an ALJ determination***. Currently, if a provider loses the second level of appeal (QIC), it must remit the funds to CMS even if the provider appeals to the ALJ level. In the wake of OMHA's decision, these funds will remain unavailable to the provider for years following the appeal to the ALJ level. The growing backlog drains an increasing amount of funds for an increasing duration from providers. Until CMS improves the appeals process, these funds should remain with the

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[3] According to a statement by Chief ALJ Nancy Griswold at a 2/12/2014 public hearing entitled "Medicare Appellant Forum." *See* Epstein Becker Green Client Alert, OMHA's Medicare Appellant Forum Offers Few Meaningful Answers for Frustrated Medicare Providers and Suppliers, February 28, 2014, at http://www.ebglaw.com/showclientalert.aspx?Show=18414.

providers through the ALJ appeals process. This is especially fair in the context of hospitals, where providers have been highly successful at the ALJ level, and have won the majority of ALJ appeals.

III. CMS and OMHA should develop and put in place long-term improvements to the Medicare audit and appeals processes on all levels of appeals

MAC Part A/B contractors have historically been expected to match denials, audits, and their appeal (redetermination) capacity; by missing the corresponding performance metrics, they are penalized or risk contract termination. The agency as a whole should follow the same practice. CMS should improve the efficiency of the audit and appeals processes by taking the following steps:

- CMS and OMHA should ***separate appeals streams by source of the payment denial*** to show whether they originate from Medicare Administrative Contractor (MAC) audits or from the RAC program. This breakdown would provide discrete information about the effectiveness of individual contractor audit processes and comparison of performance once the results of adjudication of appeals have been considered.

- CMS should also ***separate pre- and post-payment audits at the appeals level*** so that RAC post-payment audits do not overwhelm the appeals process. This would also allow CMS and OMHA to focus on solutions that target RAC audits and the resulting appeals.

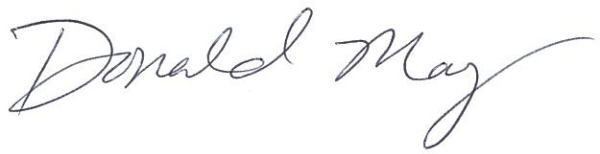
- ***A default judgment should be entered in favor of the provider if an appeal has not been heard within the required time period.*** Providers that miss appeals deadlines lose their right to pursue the claim through the appeals process. However, the only remedy that currently exists for providers when the contractors or ALJs miss their appeals deadlines is to escalate the claim to the next level of appeal. For the provider, this is no remedy at all, since significant backlogs exist at all levels of the appeals process.

- ***CMS should require RACs to request fewer medical records for review*** in order to improve the accuracy with which they select claims for review. Doing so may also encourage RACs to conduct a more thorough review that results in an accurate determination of approval or denial, thereby avoiding the need for an appeal.

- ***CMS should permit clinical inference at the redetermination and reconsideration levels of review, before the appeal for an ALJ hearing***. A comprehensive review of a claim by a clinician is a key aspect of the appeal review for claim appropriateness. Since clinical inference is currently not available until the ALJ hearing, claims ascend past the first two levels of review with little clinical feedback. If claims were examined through a clinical inference earlier in the appeal process, fewer would proceed to the cases up the appeals ladder.

We appreciate the opportunity to comment on the OMHA decision to suspend assignment of new requests for appeals for ALJ hearings. If you have any questions about our recommendations, please contact me at dmay@advamed.org or Richard Price at rprice@advamed.org.

Sincerely,



Donald May
Executive Vice President
Payment & Health Care Delivery Policy
AdvaMed

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN HOSPITAL ASSOCIATION, *et al.*, Plaintiffs, v. SYLVIA MATHEWS BURWELL, in her official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES, Defendant.	Civil Action No. 1:14-CV-851-JEB

DECLARATION OF ADAM K. LEVIN

I, Adam K. Levin, hereby declare and state the following:

1. I am a member of the Bar of the District of Columbia and am an attorney at the law firm of Hogan Lovells US LLP, counsel for Plaintiffs.

2. I submit this Declaration in support of Plaintiffs' Motion for Summary Judgment (the "Motion"). I have personal knowledge of the facts contained herein.

3. Attached to the Motion as Exhibit 1 is a demonstrative chart depicting the Medicare administrative appeals process.

4. Attached to the Motion as Exhibit 2 is a true and correct copy of a presentation by the Office of Medicare Hearings and Appeals ("OMHA") of Health and Human Services ("HHS") entitled "Medicare Appellant Forum," dated February 12, 2014, available at http://www.hhs.gov/omha/omha_medicare_appellant_forum.html (last visited July 11, 2014).

5. Attached to the Motion as Exhibit 3 is a true and correct copy of a document entitled "Memorandum to OMHA Medicare Appellants" from Nancy J. Griswold, Chief Administrative Law Judge, OMHA, dated December 24, 2013, available at

http://www.hhs.gov/omha/letter_to_medicare_appellants_from_the_calj.pdf (last visited July 11, 2014).

6. Attached to the Motion as Exhibit 4 is a true and correct copy of a printed website page entitled "*Important Notice Regarding Adjudication Timeframes*" maintained by OMHA, available at http://www.hhs.gov/omha/important_notice_regarding_adjudication_timeframes.html (last visited July 11, 2014).

7. Attached to the Motion as Exhibit 5 is a true and correct copy of a report entitled "Exploring the Impact of the RAC Program on Hospitals Nationwide: Results of AHA RAC*Trac* Survey, 1st Quarter 2014," dated May 28, 2014.

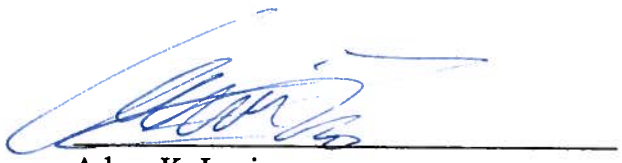
8. Attached to the Motion as Exhibit 6 is a true and correct copy of an article by Michelle M. Stein entitled "*ALJs Lay Out Path Forward For Stakeholders As Appeals Backlog Continues*" published in Inside Health Policy, and dated February 20, 2014.

9. Attached to the Motion as Exhibit 7 is a true and correct copy of a statement by Nancy J. Griswold, Chief Administrative Law Judge, OMHA, before the U.S. House Committee on Oversight and Government Reform, Subcommittee on Energy Policy, Health Care & Entitlements on July 10, 2014, entitled "Office of Medicare Hearings and Appeals Workloads," available at http://oversight.house.gov/wp-content/uploads/2014/07/CMS-Griswold-OMHA-Final.pdf (last visited July 11, 2014).

10. Attached to the Motion as Exhibit 8 is a true and correct copy of a letter dated February 12, 2014 from the American Medical Association, *et al.*, to The Honorable Nancy J. Griswold, Chief Administrative Law Judge, OMHA, available at http://www.aafp.org/dam/AAFP/documents/advocacy/payment/medicare/LT-HHS-MedicareAppealsBacklog-021214.pdf (last visited July 11, 2014).

11. Attached to the Motion as Exhibit 9 is a true and correct copy of a letter dated March 27, 2014, from Donald May, Executive Vice President of Payment & Healthcare Delivery Policy at AdvaMed, to Kathleen Sebelius, then-Secretary of HHS, and Marilyn Tavenner, Administrator of the Centers for Medicare & Medicaid Services, available at http://advamed.org/res/472/office-of-medicare-hearing-and-appeals-decision-to-suspend-assignment-of-new-request-for-administrative-law-judge-hearings-for-adjudication-of-appeals (last visited July 11, 2014).

I declare under penalty of perjury that the foregoing is true and correct. Executed this 11th day of July, 2014.



Adam K. Levin

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN HOSPITAL ASSOCIATION, *et al.*, Plaintiffs, v. SYLVIA MATHEWS BURWELL, in her official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES, Defendant.	Civil Action No. 1:14-CV-851-JEB

DECLARATION OF IVAN HOLLEMAN

I, Ivan S. Holleman, hereby declare and state the following:

1. The facts set forth in this declaration are based upon my personal knowledge. If called upon as a witness, I could and would testify to these facts.

2. I am an adult citizen of the United States and reside in Baxter County, Arkansas.

3. I am submitting this declaration on behalf of Plaintiff Baxter Regional Medical Center ("Baxter") in support of Plaintiffs' Motion for Summary Judgment.

4. I am the Chief Financial Officer ("CFO") of Baxter. My responsibilities as CFO include oversight of all financial matters related to Baxter, including management of Recovery Audit Contractor ("RAC") appeals. I have a master's degree in business administration and thirty-three years of experience in hospital finance.

Baxter and the Community It Serves

5. Baxter is licensed as a 268-bed regional hospital located in Mountain Home, Arkansas. Although Mountain Home itself is a town of only 13,000 people, Baxter serves the

259,000 residents within a 55-mile radius. Baxter has served the residents of North-Central Arkansas and South-Central Missouri for over fifty years.

6. Baxter prides itself on offering a broad range of services in thirty medical specialties, including open-heart surgery, to the community it serves. Without Baxter, patients living in the surrounding counties of North-Central Arkansas and South-Central Missouri would need to drive one to two hours for hospital care. Baxter is located fifty to one hundred miles from hospitals providing comparable services.

7. In 2013, Baxter was named by Moody's Investor Service as America's fifth-most Medicare-dependent hospital, with Medicare responsible for 65% of its gross revenue.

8. The counties served by Baxter are expected to experience an increase of 9.5% in their over-65 population between 2013 and 2018.

Baxter's ALJ Appeals

9. Baxter currently is pursuing Medicare appeals to recover approximately $4 million in reimbursement for services the hospital furnished to Medicare beneficiaries. Almost $3 million of that $4 million is pending at the Administrative Law Judge ("ALJ") level of the process.

10. Baxter currently has 230 claims pending at the ALJ level of the appeals process. Of those, 218 claims, representing $2.95 million in reimbursement, have been filed since July 15, 2013 and thus are subject to the moratorium on assignment of appeals to an ALJ. Further, 101 appeals, accounting for more than $1.2 million in Medicare reimbursement, have been pending at the ALJ level for longer than ninety days. Many of Baxter's appeals relate to denials of reimbursement for rehabilitation services.

11. Unlike at other levels of the appeal process, at ALJ hearings, Baxter has the opportunity to present oral testimony, including testimony of clinicians, in support of its claims. It also has the opportunity to respond to any questions from the ALJ in real-time through the hearing process. The ALJ level offers Baxter the first level of independent review of its claims.

12. In view of the significant advantages Baxter believes the ALJ hearing affords, Baxter does not consider escalation of its pending ALJ claims to the Departmental Appeals Board Medicare Appeals Council ("DAB") to be an adequate option. In particular, the DAB does not afford Baxter the opportunity to present testimony based on clinical factors that are critical to accurate decisions in denial of complex hospital claims.

13. Further, in all of Baxter's pending claims, the cost of litigating in federal court would far exceed the value of the claim appealed.

The Impact of the ALJ Delay on Baxter

14. The delays in the appeals process have had a crippling effect on Baxter's cash flow. Recouped funds at issue in the delayed appeals are funds that cannot be used to meet Baxter's essential needs, such as the following:

a. Purchasing basic replacement equipment, like beds for its intensive care unit;

b. Replacing a failing roof over its surgery department, which Baxter has been able only to patch; and

c. Replacing its twenty-year-old catheterization laboratory. Without renovation, this laboratory will soon need to be shut down.

15. If Baxter had access to the almost $3 million in funds that are currently subject to the ALJ delay, it would be able to address some or all of these critical needs.

16. In addition, the costs of Baxter's voluminous appeals of rehabilitation-related claim denials, combined with the delay in achieving resolution of those claims, has become so prohibitive that Baxter has considered whether it would be more financially prudent to close its rehabilitation center rather than to pursue the appeals.

17. Baxter's bond rating is also at risk. The unavailability of funds that remain pending in the appeals process has weakened Baxter's cash position, which plays a key role in issuance of bond ratings. Baxter's bond rating could easily fall to "junk bond" status if the ALJ delays continue.

I declare under penalty of perjury that the foregoing is true and correct. Executed this 11 day of July, 2014.

Ivan Holleman

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN HOSPITAL ASSOCIATION, *et al.*, Plaintiffs, v. SYLVIA MATHEWS BURWELL, in her official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES, Defendant.	Civil Action No. 1:14-CV-851-JEB

DECLARATION OF JOHN GEPPI

I, John Geppi, hereby declare and state the following:

1. The facts set forth in this declaration are based upon my personal knowledge. If called upon as a witness, I could and would testify to these facts.

2. I am an adult citizen of the United States and reside in Knoxville, Tennessee.

3. I am submitting this declaration on behalf of Plaintiff Covenant Health ("Covenant") in support of Plaintiffs' Motion for Summary Judgment.

4. I am the Executive Vice President and Chief Financial Officer for Covenant. My responsibilities as Executive Vice President/CFO include oversight of substantially all non-clinical functions for Covenant including finance, patient accounting and revenue cycle management activities. I have a Bachelor's degree in business administration and over 40 years of healthcare finance experience.

Covenant's Background

5. Covenant is a community-owned health system located in East Tennessee, consisting of nine individual hospitals: Fort Sanders Regional Medical Center, Parkwest Medical

Center, LeConte Medical Center, Methodist Medical Center of Oak Ridge, Morristown-Hamblen Healthcare System, Fort Loudoun Medical Center, Roane Medical Center (these seven hospitals collectively, "Covenant's Hospitals"), and two hospitals recently acquired in 2014, Cumberland Medical Center and Claiborne Medical Center.

6. Covenant is the largest private employer in the region. Its member hospitals are deeply involved in community and outreach programs, special events such as the Covenant Health Knoxville Marathon, and support of local charities.

7. Covenant's mission is to serve the community by improving quality of life through better health. Its vision is for its clinical and service excellence to make it the first and best choice for patients, employees, physicians, employers, volunteers, and the community.

Covenant's ALJ Appeals

8. Delays in the Medicare appeals process are making fulfillment of Covenant's mission increasingly difficult. Medicare accounts for 55% of gross revenue across Covenant's Hospitals. Covenant is currently pursuing thousands of Medicare appeals to recover millions of dollars of Medicare reimbursement for services furnished to Medicare beneficiaries. Covenant's Hospitals have more than $7.6 million in claims pending system-wide, over $7 million of which is pending at the Administrative Law Judge ("ALJ") level of the Medicare appeals process.

9. Specifically, based on the information available to me as of July 11, 2014, Covenant's Hospitals have approximately 1477 appeals currently pending at the ALJ level, of which 1445 have been pending for longer than ninety days. Further, 622 of Covenant's appeals have been filed since July 15, 2013, and are thus subject to the moratorium on assignment of appeals to an ALJ.

10. Several of Covenant's Hospitals have particularly high numbers of pending appeals. For example, based on the information available to me as of July 11, 2014, Fort Sanders Regional Medical Center ("Fort Sanders") has 381 appeals pending at the ALJ level, representing nearly $2.2 million in reimbursement: 379 of those appeals have been pending for longer than ninety days; 165 were filed after July 15, 2013 and are thus subject to the moratorium. Fort Sanders is a 541-bed regional hospital located in downtown Knoxville, Tennessee, which serves as a "regional referral center" for neurology, neurosurgery, orthopedics, oncology, cardiology, obstetrics, and rehabilitation medicine. Regional referral centers are hospitals to which other hospitals send their most difficult cases. Fort Sanders also offers specialized services such as one-day surgery, electrodiagnostics, a sleep disorders center, a diabetes management center, prenatal education, and sports medicine. Fifty-three percent of Fort Sanders' gross revenue is attributable to Medicare reimbursement.

11. Similarly, based on the information available to me as of July 11, 2014, Parkwest Medical Center ("Parkwest") has 399 appeals pending at the ALJ level, representing over $2 million in reimbursement. All of those appeals have been pending longer than ninety days, and 144 of the appeals also were filed after July 15, 2013 and are thus subject to the moratorium. Parkwest, which is located in West Knoxville, is a premier medical facility and has been named among the nation's top 100 heart hospitals eight times by Solucient. In addition to providing the area's leading cardiac services, Parkwest has a nationally recognized emergency department and offers award-winning care in orthopedics, neurosurgery, and obstetrics. Over 56% of Parkwest's gross revenue comes from Medicare reimbursement.

12. The numbers of pending appeals are subject to change. Covenant regularly monitors and updates the status of its appeals.

13. The availability of an ALJ hearing to resolve its pending appeals is of critical importance to Covenant. The ALJ level of the Medicare appeals process is the level at which Covenant has typically been able to obtain relief from claim denials. For example, since April 2011, Parkwest has been successful in 81% of its appeals decided at the ALJ level. Fort Sanders has been successful in 72% of its appeals decided at the ALJ level during the same timeframe.

14. Unlike at other appeal levels, at ALJ hearings, Covenant has been able to present oral testimony, including testimony of clinicians, in support of its claims. It has had the opportunity to respond to any questions from the ALJ in real-time through the hearing process. This process has afforded Covenant the opportunity to explain and clarify the written arguments it has submitted to the ALJ prior to hearing.

15. In view of the significant advantages Covenant believes the ALJ hearing affords, Covenant does not consider escalation of its pending ALJ claims to the Departmental Appeals Board Medicare Appeals Council ("DAB") an adequate option. Likewise, in the vast majority of Covenant's cases, the cost of litigating in federal court could far exceed the value of the claim appealed due to the increased expense related to engagement of legal counsel and other internal administrative costs needed to pursue appeal at the federal court level.

The Impact of the ALJ Delay on Covenant

16. The extended delays in obtaining a hearing and decision by an ALJ, which have been further prolonged by the moratorium on assignment of new ALJ appeals, have harmed and are continuing to harm Covenant.

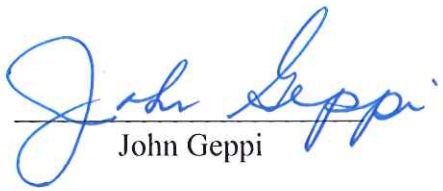
17. The delays in adjudicating these pending appeals have significantly impaired Covenant's cash flow. The over $7 million in Medicare reimbursement associated with the claims

that are pending in the Medicare appeals process is not available for Covenant's Hospitals to address patient care needs in the various communities those hospitals serve.

18. For example, Covenant is evaluating the scope of services provided to the population of patients it currently serves in light of the delays in adjudicating its appeals.

19. From January through May of 2014, Covenant's overall operating margin was negative 1.8%. The inability to recover the millions of dollars that are tied up in the appeals process is a major factor contributing to Covenant's system-wide negative operating margin.

I declare under penalty of perjury that the foregoing is true and correct. Executed this 11th day of July, 2014.



John Geppi

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN HOSPITAL ASSOCIATION, *et al.*, Plaintiffs, v. SYLVIA MATHEWS BURWELL, in her official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES, Defendant.	Civil Action No. 1:14-CV-851-JEB

DECLARATION OF CAROLINE STEINBERG

I, Caroline Steinberg, hereby declare and state the following:

1. The facts set forth in this declaration are based upon my personal knowledge. If called upon as a witness, I could and would testify to these facts.

2. I am an adult citizen of the United States and reside in Springfield, Virginia.

3. I am submitting this declaration on behalf of Plaintiff American Hospital Association ("AHA") in support of Plaintiffs' Motion for Summary Judgment.

4. I am the Vice President of Trends Analysis for the AHA. My responsibilities as Vice President of Trends Analysis include policy research and trends analysis for purposes of AHA advocacy. Specifically, my responsibilities include collaborating with federal relations, media and policy staff to develop the policy research agenda for the AHA; overseeing a team of AHA staff and external consultants to model the impact of legislative and regulatory proposals on hospitals; and acting as spokesperson for the AHA on specific topics, such as trends affecting hospitals.

5. I have twelve years of experience at the AHA. I joined the AHA in 2002 after fourteen years in health care consulting. I hold a Masters of Business Administration from the Tuck School of Business at Dartmouth and received my undergraduate degree from Harvard University.

6. The AHA is a national non-profit corporation organized and existing under the laws of the State of Illinois with offices in Chicago, Illinois, and Washington, D.C.

7. The AHA represents more than 5,000 hospitals, health care systems, and other health care organizations, plus nearly 43,000 individual members, in matters before Congress, the executive branch, and courts. The three hospital Plaintiffs, Baxter Regional Medical Center, Covenant Health, and Rutland Regional Medical Center, are AHA members.

8. The AHA's mission is to advance the health of individuals and communities by leading, representing, and serving the hospitals, health systems, and related organizations that are accountable to the community and committed to health improvement. The AHA provides extensive education for health care leaders and is a source of valuable information on health care issues and trends.

9. The AHA's member hospitals are suffering harm from the delays in the Medicare appeals process, particularly at the Administrative Law Judge ("ALJ") level. Because of the AHA's mission to serve hospitals, health systems, and related organizations, and represent their interests in judicial matters, the AHA is well-positioned to pursue this lawsuit on behalf of its members. The interests sought to be protected by this lawsuit – the timely adjudication of hospital appeals of Medicare claim denials – are directly germane to the AHA's mission and purpose, which is to ensure that members' perspectives and needs are heard in judicial matters, national health policy development, and legislative and regulatory debates.

10. As part of its mission to represent the interests of its member hospitals, the AHA created a survey to gather data regarding the impact of the Medicare Recovery Audit Contractor ("RAC") program on America's hospitals.

11. The AHA's "RAC*Trac*" survey collects data from hospitals on a quarterly basis by asking hospital members to answer questions through an online survey tool that transmits hospitals' responses electronically to the AHA. Hospitals submit data to the AHA's RAC*Trac* survey through their own claim tracking tools. Following the survey, the data are compiled and verified by independent consultants to the AHA, Booz Allen Hamilton and Provider Consulting Solutions. As a result, the AHA believes that RAC*Trac* data are reliable, accurate, and consistent.

12. Attached as Exhibit 5 to Plaintiffs' Motion for Summary Judgment is a true and correct copy of the AHA's report entitled "Exploring the Impact of the RAC Program on Hospitals Nationwide" concerning the results of its RAC*Trac* survey in the first quarter of 2014. The AHA prepared and maintained its RAC*Trac* report in the regular course of AHA's business.

13. The RAC*Trac* data attached as Exhibit 5 are the most up-to-date available data on the impact of RACs on hospitals. The most recent data made publicly available by the Centers for Medicare & Medicaid Services dates from fiscal year 2012.

14. In the first quarter of 2014, 1,165 hospitals participated in the AHA's RAC*Trac* survey. Ex. 5, RAC*Trac* Survey Results, First Quarter 2014, at 4.

15. Ninety-three percent of reporting hospitals reported experiencing at least one delay longer than the statutory limit of ninety days for an ALJ determination to be issued. *Id.* at 51.

16. Reporting hospitals reported appealing forty nine percent of all RAC denials, with a sixty-six percent success rate in the appeals process for those RAC denials. *Id.* at 4.

17. The value of appealed, RAC-denied claims reported by the AHA's survey respondents exceeds $1.8 billion. *Id.* at 47. This number does not include the value of other appealed claims, which are also subject to the ALJ moratorium, but which the AHA does not separately track.

I declare under penalty of perjury that the foregoing is true and correct. Executed this 9th day of July, 2014.

Caroline Steinberg

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN HOSPITAL ASSOCIATION, *et al.*, Plaintiffs, v. SYLVIA MATHEWS BURWELL, in her official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES, Defendant.	Civil Action No. 1:14-CV-851-JEB

DECLARATION OF JOHN WALLACE

I, John H. Wallace, hereby declare and state the following:

1. The facts set forth in this declaration are based upon my personal knowledge. If called upon as a witness, I could and would testify to these facts.

2. I am an adult citizen of the United States and reside in Rutland, Vermont.

3. I am submitting this declaration on behalf of Plaintiff Rutland Regional Medical Center ("Rutland Regional") in support of Plaintiffs' Motion for Summary Judgment.

4. I have served as Chief Compliance Officer for Rutland Regional since 2006. I was admitted to the Vermont Bar in 1999 and have worked as a health care attorney for and with Vermont hospitals for fifteen years. I also teach health care ethics and compliance at the University of Vermont.

5. As the Chief Compliance Officer, I am responsible for ensuring that Rutland Regional complies with legal and ethical standards, in particular requirements associated with federal health care programs, and that we actively prevent and detect noncompliance. I also serve as in-house legal counsel. Since the development of the Medicare Recovery Audit

Contractor ("RAC") program, I have been responsible for overseeing our response to external audits.

Rutland Regional and the Community It Serves

6. Rutland Regional is licensed as a 188-bed, community-owned rural hospital located in Rutland, Vermont. Despite its small size, Rutland Regional is the second largest hospital in the state of Vermont.

7. Rutland Regional offers the full scope of community hospital services, and has several outpatient specialty clinics including the Foley Cancer Center, The Rutland Heart Center, Rutland Women's health clinic, Rutland Diabetes and Endocrinology Center, the Vermont Orthopaedic Clinic, the ENT and Audiology Clinic, and Rutland Behavioral Health. Rutland Regional also provides uniquely important services to the community it serves, such as the newly opened West Ridge Center for Addiction Recovery. (Vermont ranks in the top ten of states for several measures of substance abuse. Rutland was recently featured on the front page of the *New York Times*. *See* Katharine Q. Seelye, *A Call to Arms on a Vermont Heroin Epidemic*, N.Y. TIMES, Feb. 27, 2014, at A1, available at http://www.nytimes.com/2014/02/28/us/a-call-to-arms-on-a-vermont-heroin-epidemic.html?_r=0.) Further, in 2011, Rutland Regional expanded its inpatient psychiatric services and assumed responsibility for patients that were displaced when the state's psychiatric hospital closed after flooding from Hurricane Irene.

8. More than 60,000 residents of Vermont and New York depend on Rutland Regional for hospital services. In fact, the Secretary of Health and Human Services ("HHS") has classified Rutland Regional as a "sole community hospital" pursuant to 42 U.S.C. § 1395ww(d)(5)(D)(iii) and 42 C.F.R. § 412.92. The "sole community hospital" program is intended to maintain access to hospital services for Medicare beneficiaries in areas of geographic

isolation. HHS also has designated Rutland Regional as a "Rural Referral Center" because of the severity of cases it treats and the specialized physicians it provides to treat those cases.

9. Rutland Regional services an aging community with a large proportion of Medicare beneficiaries. In 2000, 14.9% of the population of Rutland County was age sixty-five or older. That number has grown to 16.6% in 2010 and is expected to continue to rise. By 2017, it is expected that 21.1% of Rutland County's population will be age sixty-five or older.

10. Moreover, in 2007, 20.9% of Rutland County's residents were Medicare beneficiaries, a higher percentage than the state of Vermont as a whole (17.2%). In fiscal year 2013, Medicare was responsible for approximately 47% of Rutland Regional's gross revenues.

Rutland Regional's ALJ Appeals

11. Rutland Regional currently is pursuing Medicare appeals to recover approximately $588,000 in Medicare reimbursement, of which approximately $554,000 is pending at the Administrative Law Judge ("ALJ") level of the process.

12. Rutland Regional currently has ninety-eight appeals pending at the ALJ level. Ninety-six of the ninety-eight appeals have been pending for more than ninety days. Fifty-four of the ninety-eight appeals were filed on or after July 15, 2013 and are subject to HHS's moratorium on assignment of appeals to ALJs.

13. Of the ninety-six appeals that have been pending for more than ninety days, fifty-eight are appeals from denials by RACs. Most of Rutland Regional's appeals involve determinations by a Medicare contractor, such as a RAC, that a Medicare beneficiary who received treatment during an inpatient stay at Rutland Regional could have been treated as an outpatient instead.

14. Unlike at other levels of the appeal process, at ALJ hearings, Rutland Regional has the opportunity to present oral testimony, including testimony of clinicians, in support of its claims. It also has the opportunity to respond to any questions from the ALJ in real-time through the hearing process. The ALJ level offers Rutland Regional the first level of independent review of its claims.

15. Rutland Regional has also received detailed findings of fact and conclusions of law from ALJs when decisions have been rendered. Attached as Exhibits A, B, and C are true and correct copies of decisions Rutland Regional has received at the first three levels of appeal before the Medicare Administrative Contractor ("MAC"), Qualified Independent Contractor ("QIC"), and ALJ regarding the same patient care, redacted only to protect patient information. *Compare* Ex. A (MAC decision dated August 27, 2012) (offering two-paragraph explanation of decision in rendering denial) *with* Ex. B (QIC decision dated January 17, 2013) (offering approximately two-page explanation of decision in affirming denial for same patient care) *and* Ex. C (ALJ decision dated June 25, 2013) (providing eleven pages of findings of fact and conclusions of law in rendering wholly favorable decision for same patient care).

16. In view of the significant advantages Rutland Regional believes the ALJ hearing affords, Rutland Regional does not consider escalation of its pending ALJ claims to the Departmental Appeals Board Medicare Appeals Council to be an adequate option. Likewise, in all of Rutland Regional's pending cases, the cost of litigating in federal court would far exceed the value of the claim appealed.

The Impact of the ALJ Delay on Rutland Regional

17. HHS's extended delays, which have been further prolonged by the moratorium on the assignment of new ALJ appeals, have harmed and are continuing to harm Rutland Regional.

18. If Rutland Regional had access to the over $500,000 in funds that are subject to the ALJ delay, it could use those funds to advance its mission and enhance patient care, and create new clinics and programs.

19. Rutland Regional has had to implement a number of cost-cutting measures to accommodate the cash flow deficiencies caused, in part, by these delays. Rutland Regional initiated two rounds of cost-reductions that resulted in the elimination of thirty-two jobs. The community has been affected both through the loss of jobs and by the limitation on Rutland Regional's ability to serve its mission to improve the health of the community.

I declare under penalty of perjury that the foregoing is true and correct. Executed this 11th day of July, 2014.

John Wallace

EXHIBIT A

Level 1 appeal denied.

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

MEDICARE NUMBER OF BENEFICIARY
[redacted]

MEDICARE APPEAL DECISION

RECEIVED
AUG 30 2012
RRMC UTILIZATION

CONTACT INFORMATION
If you have questions, write or call:
NHIC-MAC J14
MEDICARE PART A APPEALS
P. O. BOX 9202
HINGHAM, MA 02044
PROVIDER PART A: 1-877-757-7783
BENEFICIARY: 1-800-633-4227

FNHRDL2P00000025
NANCY COTA
RUTLAND REGIONAL MEDICAL CENTER
160 ALLEN STREET
RUTLAND, VT 05701

DATE: 08/27/12

PROVIDER NPI: 1720042203 PROVIDER NUM: 470005
HIC: [redacted]
BENEFICIARY: [redacted]
DATES OF SERVICE, FROM: [redacted] THRU: [redacted]
SERVICES PROVIDED BY: THE RUTLAND HOSPITAL, INC.
SERVICES PROVIDED TO: [redacted]
DOCUMENT CONTROL NUMBER: [redacted] TYPE BILL: 110

Dear Ms. Cota,

This letter is to inform you of the decision on your Medicare Appeal. An appeal is a new and independent review of a claim. You are receiving this letter because you requested an appeal.

The appeal decision is unfavorable. Our decision is that your claim is not covered by Medicare.

More information on the decision is provided below. If you disagree with the decision, you may appeal to a Qualified Independent Contractor (QIC). You must file your appeal, in writing, within 180 days of receiving this letter. The Reconsideration Request Form is attached to help with this process. However, if you do not wish to appeal this decision, you are not required to take any action.

NHIC, Corp. was contracted by Medicare to review your appeal. For more information on how to appeal, see the section titled "Important Information About Your Appeal Rights." A copy of this letter was also sent to Mary Nickerson.

Summary of the Facts

Rutland Regional Medical Center submitted a claim for inpatient hospital services provided from [redacted] 13, [redacted] through [redacted] 14, [redacted] An initial determination on the claim was made on June 7, 2012. The claim was denied because the information provided did not support the admission to the hospital as being medically necessary. On July 16, 2012, we received a request for a redetermination. A letter from a hospital representative and oncology notes were included with the appeal request. The documentation previously submitted to the Medical Review Department was also included in the redetermination process.

DATE: 08/27/12

[redacted]

Decision

We have decided that the above services are not covered by Medicare. We have also decided that the provider is responsible for payment of the noncovered services.

Explanation of the Decision

Our review of the records was based on the Internet-Only Manuals (IOM) Pub 100-2, Medicare Benefit Policy Manual, Chapter 1, Section 10 and 100-8, Medicare Program Integrity Manual, Chapter 6, Section 6.5. Inpatient care rather than outpatient care is required only if the patient's medical condition, safety, or health would be significantly and directly threatened if care was provided in a less intensive setting. The patient's signs and symptoms must be severe enough to warrant the need for medical care and must receive services of such intensity that they can be furnished safely and effectively only on an inpatient basis.

[redacted] arrived at the hospital complaining of malaise and shortness of breath. [redacted] had a medical history that included [redacted] cancer with metastasis to the liver. Upon presentation [redacted] sodium level was found to be low, and [redacted] was in no acute cardiopulmonary distress. The diagnostic scan of [redacted] brain was negative, and the scan of [redacted] abdomen showed mild metastatic disease progression. [redacted] white blood cell count was elevated, and [redacted] chest X-ray was negative for any acute infiltrates. There were also some notes indicating that [redacted] was anemic, and that a blood transfusion was to be ordered. [redacted] treatment plan included intravenous fluids, antibiotics, and a respiratory therapy consultation. [redacted] symptoms improved, and [redacted] was discharged in stable condition. The treatment provided could have been safely managed at an observation level of care. Inpatient care is only required if the patient's condition, safety, or health would be significantly threatened if care was given in a less intensive setting.

Who is Responsible for the Bill?

After reaching a decision that the service/item will not be covered by Medicare, we must decide who is liable for the denied service/item. The instructions contained in Section 1879 of the Social Security Act require two steps. First, we must decide if the beneficiary either knew or could reasonably be expected to know that the service/item would not be covered under 1862(a)(1) or 1862 (a)(9) of the Social Security Act. Next, we must decide if the provider either knew or could reasonably be expected to know that the service/item would not be covered under 1862(a)(1) or 1862(a)(9) of the Social Security Act.

By following these instructions, we have decided that the provider either knew or could be reasonably expected to know that the service/item would not be covered. 42 Code of Federal Regulations (CFR) 411.406 states that providers are presumed to have knowledge of published Medicare rules and

DATE: 08/27/12

[redacted]

regulations, CMS rulings, Medicare coverage policies in contractor bulletins or websites and acceptable standards of medical care in the community. The provider has received notices and directives (such as bulletins, Change Requests, Medicare Memos, and Local Coverage Determinations) from CMS and this contractor. These have included instructions on how to access the Medicare Internet-Only Manuals (IOMs).

Therefore, the beneficiary is not responsible for the charges billed by the provider except for any charges for services never covered by Medicare. If the beneficiary has paid the provider for these services (including payment of co-insurance and deductible), the beneficiary may be entitled to a refund. To get this refund, please send the following items to this office:

* A copy of this notice
* The bill the patient received for the services, and
* The payment receipt, the cancelled check, or any other evidence showing that the beneficiary has already paid for the services at issue.

The beneficiary should file the written request for refund within 6 months of the date of this notice.

What to Include in Your Request for an Independent Appeal

We believe we have all the evidence needed to make a decision. The documentation does not support the need for the service. However, you may still send additional information to explain why this service should be paid.

Special Note to Medicare Physicians, Providers, and Suppliers Only

Any additional evidence should be submitted with the request for reconsideration. All evidence must be presented before the reconsideration is issued. If all evidence is not submitted prior to the issuance of the reconsideration decision, you will not be able to submit any new evidence to the Administrative Law Judge or further appeal unless you can demonstrate good cause for withholding the evidence from the QIC.

NOTE: You do not need to resubmit documentation that was submitted as part of the redetermination. This information will be forwarded to the QIC as part of the case file utilized in the reconsideration process.

Sincerely,

Jennifer R. Murgia, LPN, AA

NHIC-A/B MAC J14
Medicare Part A

[redacted]

Medicare Part A

IMPORTANT INFORMATION ABOUT YOUR APPEAL RIGHTS

Your Right to Appeal this Decision: If you do not agree with this decision, you may file an appeal. An appeal is a review performed by people independent of those who have reviewed your claim so far. The next level of appeal is called reconsideration. A reconsideration is a new and impartial review performed by a company that is independent from NHIC, Corp.

How to Appeal: To exercise your right to an appeal, you must file a request in writing within 180 days of receiving this letter. Under special circumstances, you may ask for more time to request an appeal. You may request an appeal by using the form enclosed with this letter.

If you do not use this form, you may write a letter. You must include: your name, your signature, the name of the beneficiary, the Medicare number, a list of the service(s) or item(s) that you are appealing and the dates(s) of service, and any evidence you wish to attach. You must also indicate that NHIC, Corp. made the redetermination. You may also attach supporting materials, such as those listed in item 10 of the enclosed Reconsideration Request Form, or other information that explains why this service should be paid. Your doctor may be able to provide supporting materials.

If you want to file an appeal, you should send your request to :

MAXIMUS FEDERAL SERVICES
MEDICARE PART A EAST
3750 MONROE AVE, SUITE 701
PITTSFORD, NY 14534-1302

Who May File an Appeal: You or someone you name to act for you (**your appointed representative**) may file an appeal. You can name a relative, friend, advocate, attorney, doctor, or someone else to act for you.

If you want someone to act for you, you may visit *http://www.medicare.gov/basics/forms/default.asp* to download the "Appointment of Representative" form, which may be used to appoint a representative. Medicare does not require that you use this form to appoint a representative. Alternately, you may submit a written statement containing the same information indicated on the form. If you are a Medicare enrollee, you may also call 1-800MEDICARE (1-800-633-4227) to learn more about how to name a representative.

Other Important Information: If you want copies of the statutes, regulations, policies, and/or manual instructions, we used to arrive at this decision, or if you have any questions specifically related to your appeal, please write to us at the following address and attach a copy of this letter:

NHIC A/B MAC J14
P. O. BOX 1000
HINGHAM, MA 02044

Resources for Medicare Enrollees: If you want help with an appeal, or if you have questions about Medicare, you can have a friend or someone else help you with your appeal. You can also contact your State Health Insurance Assistance Program (SHIP). You can find the phone number for your SHIP in your "Medicare & You" handbook, under the "Helpful Contacts" section of *www.medicare.gov* Web site, or by calling 1-800-MEDICARE (1-800-633-4227). Your SHIP can answer questions about payment denials and appeals.

For general questions about Medicare, you can call 1-800-MEDICARE (1-800-633-4227), TTY/TDD: 1-877-486-2048.

Remember that specific questions about your appeal should be directed to the contractor that is processing your appeal.

EXHIBIT B

6265996

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

RECEIVED
JAN 30 2013
RRMC UTILIZATION

[redacted]

MAXIMUS
Federal Services

If you have questions, write or call:

MAXIMUS
Federal Services
QIC Part A East
3750 Monroe Ave
Suite 701
Pittsford, NY
14534-1302

Provider Inquiries

Visit: www.q2a.com
Or
Call: 585-348-3200

Beneficiary Inquiries

Call:

1-800-MEDICARE
Or
1-800-633-4227

Who we are:

We are MAXIMUS Federal Services. We are experts on appeals. Medicare hired us to review your file and make an independent decision.

RUTLAND REGIONAL MEDICAL CENTER
160 ALLEN ST
RUTLAND, VT 05701

ADR FY12 Q3

January 17, 2013

RE: Beneficiary: [redacted]
HIC #: [redacted]
Appellant: Rutland Regional Medical Center

Dear Rutland Regional Medical Center:

This letter is to inform you of the decision on your Medicare Appeal. An appeal is a new and independent review of a claim. You are receiving this letter because you requested an appeal for inpatient services provided to [redacted] the beneficiary, on [redacted] 13, [redacted] to [redacted] 14, [redacted].

The appeal decision is unfavorable. Our decision is that your claim is not covered by Medicare. We have determined that the provider is liable. Please see below regarding further appeal rights.

More information on the decision is provided below. You are not required to take any action. However, if you disagree with the decision, you may appeal to an Administrative Law Judge (ALJ). You must file your appeal, in writing, within 60 days of receipt of this letter. For more information on how to appeal, see the page titled "Important Information About Your Appeal Rights." The amount still in dispute is estimated to exceed the amount required to file an appeal at the ALJ Hearing level.

A copy of this letter was also sent to the beneficiary.

MAXIMUS Federal Services (MAXIMUS) was contracted by Medicare to review your appeal.

v2.0

Appeal Details at Issue

Document Control Number	Provider	Dates of Service
[redacted]	Rutland Regional Medical Center	[redacted] 13, [redacted] to [redacted] 14, [redacted]

Summary of the Facts

Rutland Regional Medical Center, the provider, billed for inpatient services provided to the beneficiary on [redacted] 13, [redacted] to [redacted] 14, [redacted]. Upon initial determination, NHIC, Corp., the Medicare Administrative Contractor with jurisdiction, denied payment for the services. At redetermination NHIC, Corp. denied payment for services again. MAXIMUS received a request for reconsideration on September 20, 2012.

Decision

We have determined that Medicare does not cover the claim for the inpatient services provided to the beneficiary on [redacted] 13, [redacted] to [redacted] 14, [redacted]. We have also determined that the provider is responsible for payment for the inpatient services at issue.

Explanation of the Decision

The issue is whether the inpatient services provided to the beneficiary on [redacted] 13, [redacted] to [redacted] 14, [redacted] met Medicare criteria for coverage.

Inpatient hospital care, rather than hospital outpatient care, is required only if the beneficiary's medical condition, safety, or health would be significantly and directly threatened if care was provided in a less intensive setting. For inpatient care, the medical record must indicate that inpatient care was medically necessary, reasonable, and appropriate for the diagnosis and condition of the beneficiary at any time during the stay. The beneficiary must demonstrate signs and/or symptoms severe enough to warrant the need for medical care and must receive services of such intensity that they can be furnished safely and effectively only on an inpatient basis. (Medicare Program Integrity Manual, Publication 100-8, Chapter 6, Section 6.5.2)

For inpatient hospital care, admitting physicians or other practitioners should use a 24-hour period as a benchmark, i.e., they should order inpatient admission for patients who are expected to need such care for 24 hours or more, and treat other patients on an outpatient basis. However, the decision whether to admit as an inpatient is a complex medical judgment, which includes consideration of a variety of factors, including:

- The patient's medical history and current medical needs;
- The types of facilities available to inpatients and outpatients, the hospital's bylaws and admission policies, and the relative appropriateness of treatment in each setting;

- The severity of the signs and symptoms exhibited by the beneficiary;
- The medical probability of something adverse happening to the beneficiary;
- The need for diagnostic studies that are appropriately outpatient services to assist in assessing the need for inpatient admission; and
- The availability of diagnostic procedures at the time when and at the location where the beneficiary presents.

(Medicare Benefit Policy Manual, Publication 100-2, Chapter 1, Section 10).

Outpatient observation care is a well-defined set of specific, clinically appropriate services, which include ongoing short term treatment, assessment, and reassessment before a decision can be made regarding whether a patient will require further treatment as a hospital inpatient, or if s/he can be discharged from the hospital. Thus, a patient receiving hospital observation services may improve and be released, or be admitted as an inpatient. In the majority of cases, the decision whether to admit as an inpatient or discharge can be made in less than 48 hours, usually in less than 24 hours. (Medicare Benefit Policy Manual, Publication 100-2, Chapter 6, Section 20.6; Medicare Claims Processing Manual, Publication 100-4, Chapter 4, Section 290).

In this case, NHIC, Corp. determined that argued that the beneficiary did not require an inpatient level of care. When requesting this appeal, the appellant argued that the beneficiary required an inpatient admission.

A panel of licensed healthcare professionals reviewed this case and determined that the services at issue did not meet Medicare coverage criteria.

The beneficiary has a medical history significant for asthma, malignant neoplasm of the [redacted] [diagnosed in 2006] with metastasis to the liver, six year history of multiple chemotherapeutic treatments. Most recently, the beneficiary received chemotherapy on [redacted], 2012 with Carboplantin and Gemcitabine followed by 1.5 mg of Pegfilgrastim. It is reported that the beneficiary was seen in clinic [cancer center] the day before and received intravenous hydration for volume depletion and anemia. The beneficiary was scheduled to receive two units of packed red blood cells on [redacted], 2012.

On [redacted], 2012 the beneficiary was brought into clinic for evaluation of increased abdominal pain and confusion. On presentation the beneficiary was awake, alert, orientated in no acute distress, febrile [100.76], review of systems was noncontributory, white blood cell count was 16 k/ul. The beneficiary was admitted as an inpatient on [redacted], 2012 with orders for intravenous hydration, pain management, blood transfusions [two units of packed red blood cells], radiological studies to assess metastatic disease or other etiology [computed tomography (CT) scan showed some mild disease progression], oncology social worker and case management.

Medicare criteria for inpatient admission was not met since the services rendered to the beneficiary were not high acuity services and none of the beneficiary's testing results revealed pathology that required complex therapy or that prompted urgent intervention. Finally, no complicating event occurred during the course of the hospital stay to require an escalation in the beneficiary's level of care, or to necessitate more intense monitoring. The beneficiary was discharged from the hospital on [redacted] 2012 with plans to follow up at a later date.

The denial is upheld.

The inpatient hospital services at issue were not reasonable and medically necessary. The beneficiary must demonstrate signs and/or symptoms severe enough to warrant medical care and must receive services of such intensity that they could be furnished safely and effectively only on an inpatient basis. The documentation submitted for review did not support that the beneficiary required an inpatient level of care. Therefore, Medicare cannot cover the inpatient hospital services at issue.

Additional Information

Medicare requires that all evidence be presented before the reconsideration is issued. On further appeal, an ALJ will not consider any new evidence unless you show good cause for not presenting the evidence to the Qualified Independent Contractor (QIC). This requirement does not apply to beneficiaries, unless a provider or supplier represents the beneficiary. (42 Code of Federal Regulations Section 405.966).

You can receive copies of statutes, regulations, policies, and/or manual instructions we used to arrive at this decision. For instructions on how to do this, please see 'Other Important Information' on the page titled "Important Information About Your Appeal Rights."

Who is Responsible for the Bill?

Because we determined that the services in question did not meet Medicare coverage criteria, under the Social Security Act, Title 18, Section 1879, we must determine whether the beneficiary and/or provider knew or could reasonably have been expected to know that the services would not be covered under Medicare.

The case file did not include an Advance Beneficiary Notice or any other documentation that the beneficiary had been given prior written notice that Medicare would not pay for the inpatient services at issue. Therefore, we have concluded that the beneficiary in this case did not know, or could not reasonably have known, that any of these items or services would not be covered by Medicare, and the beneficiary is not financially responsible for these noncovered charges.

Since we have found that the beneficiary is not liable, we must next determine whether the provider should be held liable for any of these noncovered items or services. The provider has received or has access to CMS notices, including manual issuances, bulletins, or other written guides or directives from Medicare contractors, describing the basis for excluding certain services from Medicare coverage. Similarly, the provider has access to Federal Register publications containing notice of national coverage decisions or of other specifications regarding noncoverage of an item or service. Therefore, we have determined that the Rutland Regional Medical Center is responsible for payment of the inpatient services because it knew, or could reasonably have been expected to know, that Medicare payment for the service or

item would be denied. (CMS Medicare Claims Processing Manual, Publication 100-4, Chapter 30, Section 40.1).

If you have any questions, please call the phone number on the front of this letter. For information on how to appeal this decision, please see the page entitled "Important Information About Your Appeal Rights."

Sincerely,

Barbara M. Yakimowicz, J.D., M.H.A., PMP
Project Director

BMY/MKR

cc:

[redacted]

v2.0

IMPORTANT INFORMATION ABOUT YOUR APPEAL RIGHTS

Your Right to Appeal this Decision

If you do not agree with this decision, you may file an appeal. An appeal is a review performed by people independent of those that have reviewed your claim so far. The next level of appeal is called an Administrative Law Judge (ALJ) Hearing. At this hearing, you or your representative may present your case before a judge.

If you appeal before January 1, 2013, you must have at least $130 still in dispute. If you appeal after January 1, 2013, you must have at least $140 still in dispute. This appeal can be combined with others to reach this total, if the other claims were appealed and dismissed within 60 day of this new request for an appeal, and involve similar or related services.

How to Appeal

To exercise your right to appeal, you must file a request in writing within **60 days** of receiving this letter. You must send your request to:

HHS OMHA Centralized Docketing
200 Public Square, Suite 1260
Cleveland, OH 44114-2316

You should use FORM CMS-20034 A/B, available at:

http://www.hhs.gov/omha/forms/index.html

Your written request must include: (1) The name, address, and Medicare health insurance claim number of the beneficiary, (2) The name and address of the person appealing, if the person is not the beneficiary, (3) The name and address of the representative, if any, (4) The appeal number listed on the front page of this notice, (5) The dates of service, (6) The reasons why you disagree with the decision, (7) Any and all evidence you wish to submit and the date it will be submitted, (8) A statement that you have sent a copy of this request to the other parties to the appeal, and (9) If you wish to combine claims to meet the ALJ Hearing minimum amount in dispute, include a list of the claims.

Under special circumstances, you may ask for more time to request an appeal.

Upon receipt of your request, the ALJ may decide a hearing is necessary for your appeal. ALJ hearings are usually held by telephone or video-teleconference (VTC) to make sure you get a hearing and decision as fast as possible.

Telephone or VTC hearings reduce travel time for you, ALJs, and witnesses. If you do not want a telephone or VTC hearing, you may ask for a hearing in person, which the ALJ may grant for good cause. Your request must be in writing. Your request must explain why you believe an in-person hearing is necessary.

Who May File an Appeal

You or someone you name to act for you (your **appointed representative**) may file an appeal. You can name a relative, friend, advocate, attorney, doctor, or someone else to act for you.

If you want someone to act for you, you and your appointed representative must sign, date and send us a statement naming that person to act for you. Call 1-800-MEDICARE to learn more about how to name a representative.

Help With Your Appeal

If you want help with an appeal, or if you have questions about Medicare, you can have a friend or someone else help you with your appeal. You can also contact your State Health Insurance Assistance Program (SHIP). You can call 1-800-MEDICARE (1-800-633-4227) for information on how to contact your local SHIP. Your SHIP can answer questions about payment denials and appeals.

Other Important Information

If you want copies of statutes, regulations, policies, and/or manual instructions we used to arrive at this decision, please write to us at the following address and attach a copy of this letter:

MAXIMUS Federal Services
QIC Part A East
3750 Monroe Ave, Suite 701
Pittsford, NY 14534-1302

If you need more information or have any questions, please call us at the phone number provided on the front of this notice.

Other Resources To Help You

1-800-MEDICARE (1-800-633-4227),
TTY/TDD: 1-800-486-2048

EXHIBIT C

[redacted]

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Midwestern Region
Cleveland, Ohio

WHOLLY FAVORABLE DECISION

Appeal of: **E.H.R. o.b.o. Rutland Regional Medical Center**	ALJ Appeal No.: [redacted]
Beneficiary: [redacted]	**Medicare Part A**
HICN: [redacted]	Before: **James S. O'Leary** U.S. Administrative Law Judge

Summary of Decision

Executive Health Resources is the Authorized Representative of Appellant. Rutland Regional Medical Center (Provider, Appellant) provided medical services (Part A Inpatient Hospital Admission) to [redacted] (Beneficiary) for dates of service (DOS) [redacted] 13, [redacted] to [redacted] 14, [redacted]; in satisfaction of Medicare coverage criteria, thus warranting this Wholly Favorable decision.

Procedural History

Appellant provided medical services (Part A Inpatient Hospital Admission) to Beneficiary for DOS [redacted] 13, [redacted] to [redacted] 14, [redacted] and sought Medicare coverage and reimbursement. Medicare, by NHIC (Carrier) initially denied the claims and again denied the claims in a Redetermination Decision of August 27, 2012 (Exh. 2, pp. 20-26). Medicare Qualified Independent Contractor Maximus Federal Services denied the claims in a Reconsideration Decision of January 17, 2013 (Exh. 2, pp. 6-11). A timely Request for ALJ Hearing was filed on March 14, 2013 (Exh. 2, pp. 6-11; Exh. 2, pp. 1-4; 42 C.F.R. §405.1002; 42 C.F.R. §405.1004; 42 C.F.R. §405.1014). No hearing has been held. This Wholly Favorable decision follows (Exhs. 1-2; 42 C.F.R. §405.1038).

Issues

The Carrier denied the claims stating the records do not show why the services (Part A Inpatient Hospital Admission) could not have been safely provided in another setting (e.g. observation status or as an outpatient). The QIC denied the claim with similar reasoning (Exhs. 1-2; Exh. 2, pp. 20-26; Exh. 2, pp. 6-11). The issues to be decided by this Appeal are:

- Did Appellant prove the [redacted] 13, [redacted] to [redacted] 14, [redacted] inpatient hospital admission of Beneficiary was medically reasonable and necessary, thus warranting Medicare coverage and reimbursement at the level claimed?

Findings of Fact

The following facts were established by a preponderance of the evidence: These claims have been denied by the Carrier and the QIC. Appellant's appeal is now before this ALJ on a

timely filed appeal (Exh. 2, pp. 20-26; Exh. 2, pp. 6-11; Exh. 2, pp. 1-4; 42 C.F.R. §405.1002; 42 C.F.R. §405.1004; 42 C.F.R. §405.1014), which satisfies the amount in controversy (Exhs. 1-2; Exh. 2, p. 31; 42 C.F.R. §405.1006; 77 Federal Register (Fed.Reg.) No. 189, §59618-§59619 (September 28, 2012)).

On DOS Beneficiary was a 66 year old [redacted] who presented to the ED/ER complaining of Shortness of Breath (SOB) and Fatigue. In the ER test showed [redacted] Hypotensive (80/40); Febrile (WBC count 16,000). [redacted] past medical history and other conditions include: Recurrent [redacted] Cancer with Multiple Metastases (including to the liver); Asthma; Last Chemotherapy was [redacted]/06/[redacted] (needed IV hydration the day before for volume depletion and anemia) (Exh. 1, pp. 1-101; Exh. 2, pp. 18-19; *International Classification of Diseases Clinical Modification*, for Physicians, Vols. 1 & 2, Pro. Ed. 2011, Ingenix, (*ICD-9*)). On DOS Beneficiary was admitted to Provider's hospital as an inpatient for DOS [redacted] 13, [redacted] to [redacted] 14, [redacted] Beneficiary was admitted for IV Hydration, Pain Management, and to receive Blood Transfusions (scheduled to receive 2 units on [redacted] 14/[redacted]. Beneficiary was discharged when Beneficiary's physical examination and test results were again within normal limitations, showing Beneficiary was stable and had returned to baseline (Exh. 1, pp. 1-101; Exh. 2, pp. 18-19).

Appellant, in furtherance of making their position better appreciated, has provided a Position Paper which argues:

> This inpatient hospital admission was medically necessary, appropriate and consistent with the best local and national standards of medical practice. The medical record documents the following evidence which unquestionably shows that this admission fulfilled the Medicare requirements for an inpatient hospital admission under the CMS *Medicare Benefit Policy Manual (MBPM)*, pub. 100-02, Ch. 1, §10, as well as other noted CMS regulations and guidance.
> (Exh. 1, pp. 1-101; Exh. 2, pp. 18-19).

No Advanced Beneficiary Notice (ABN) appears in the file (Exhs. 1-2; §1879(a) of the Act, 42 USCA §1395pp; 42 C.F.R.§411.400- §411.408). Appellant has submitted additional records for consideration, including a Position Paper (Exhs. 1-2; Exh. 2, pp. 18-19; Exh. 2, pp. 1-32; 42 C.F.R. §405.1028; 42 C.F.R. §405.1018).

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

An individual or organization that is dissatisfied with the reconsideration of a Qualified Independent Contractor (QIC) or of a Medicare Quality Improvement Organization (QIO) is entitled to a hearing before the Secretary of the Department of Health and Human Services (hereinafter "HHS" and the "Secretary"), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner (Social Security Act (hereinafter Act) §1869(b)(1)(A), 42 USCA §1395ff). The Secretary has delegated his authority to administer the nationwide hearings and appeals system for the Medicare program to the Office of Medicare Hearings and Appeals ("OMHA") (§1869 of the Act, 42 USCA §1395ff; 42 C.F.R. §405.904; 70 Federal Register (Fed.Reg.) §36386, §36387 (06/23/05)). The ALJs within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council or Federal District Courts (See 42 C.F.R. §405.1048).

[redacted]

B. Scope of and Standard of Review

The issues before the ALJ include all the issues brought out in the initial determination, Redetermination, or Reconsideration decisions that were not decided entirely in Appellant's favor. An ALJ may also consider and rule on issues not appealed by Appellant, if evidence causes the ALJ to question a previously wholly favorable decision. The ALJ may consider and rule on this issue as a 'new issue' provided the ALJ notifies all of the parties before the Hearing (42 C.F.R. §405.1032). ALJs are empowered to conduct *de novo* considerations of the facts and the law (See §1869 of the Act, 42 USCA §13955ff; 42 C.F.R. §405.904; 70 Fed. Reg. §36386, §36387 (June 23, 2005)).

II. Principles of Law

A. Statutes & Regulations

Benefits for Medicare Part A include services provided to a Beneficiary as an inpatient in a hospital. Benefits for Medicare Part B include "medical and other health services" which includes diagnostic services which are (1) furnished to people as outpatients by a hospital or under arrangements with them made by a hospital and (2) such services are ordinarily furnished by the hospital to its patients for diagnostic study. Coverage for 'outpatient' observation services provided by hospitals to patients not yet admitted as 'inpatients' or discharged, is included in this grouping of services (§1861(s)(2)(B)(C), 42 USCA §1395x).

All Medicare coverage must always be measured by the standard that no payment may be made under Part A (hospital insurance) or Part B (supplementary medical insurance) for any expenses incurred for items or services that are not 'reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member' (§1862(a)(1)(A) of the Act, 42 USCA §1395y). Any potential payment of benefits must always be supported by sufficient information and documentation (§1833(e) of the Act, 42 USCA §1395l).

A party requesting an ALJ Hearing must do so within 60 days of receipt of the notice of the QIC's Reconsideration Decision. The party is presumed to have received the QIC's decision 5 days after the date of the Reconsideration Decision, unless there is evidence to the contrary. The Request for ALJ Hearing is considered filed when it is received by the entity specified in the QIC's Reconsideration Decision or if it is filed in a timely manner with another entity by virtue of a good faith mistake (42 C.F.R. §405.1002; 42 C.F.R. §405.1014). If a party files a RFH after the 60 days have elapsed, they may request an extension of time to file and be considered timely if the ALJ finds good cause for the delayed filing (42 C.F.R. §405.1014(c); 42 C.F.R. 405.942).

Appellants must submit the evidence to be considered in a timely manner. Absent a finding of good cause by the ALJ, the evidence is late unless it was submitted before the issuance of the QIC's Reconsideration Decision (42 C.F.R. §405.966; 42 C.F.R. §405.1018; 42 C.F.R. §405.1028; 42 C.F.R. §405.942).

Providers are presumed to know the rules of Medicare, and what will or will not be covered. If neither the Provider nor the Beneficiary could reasonably have been expected to know something would not have been covered, then Medicare may cover it. If it is not covered, the Provider is presumed to be responsible, since they should have known it would not be covered. A Beneficiary can be held liable for payment for non-covered services if a valid written

notice, Advanced Beneficiary Notice (ABN) or Notice of Non-Coverage, is provided to them in accordance with law (42 C.F.R. §411.400-§411.408; §1879 of the Act, 42 USCA §1395pp; *Medicare Claims Processing Manual (MCPM)* pub. 100-04, Ch. 30).

Section 1879 of the Act, provides for shifting of liability and for payment in cases where neither the Beneficiary or the Provider knew or had reason to know the goods and services would not be covered (§1879 of the Act, 42 USCA §1395pp).

B. Policy and Guidance

The Act states that unless promulgated as a regulation by the Secretary, no rule, requirement, or statement of policy, other than a *National Coverage Determination (NCD)*, can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare Program (§1871(a)(2) of the Act, 42 USCA §1395hh; 42 C.F.R. §405.860). The Centers for Medicare and Medicaid Services (CMS) provide manuals for guidance in the administration of the Medicare Program. CMS approved contractors issue *Local Medical Review Policies* (*LMRPs*) and *Local Coverage Determinations (LCDs)*. The Medicare manuals, *LMRP*s, and *LCD*s are not binding on ALJs, but are entitled to "substantial deference" (42 C.F.R. §405.1062; *Shalala v. Guernsey Memorial Hospital*, 514 U.S. 87, 102 (1995). No *LCD* was cited by the Carrier or the QIC.

The *Medicare Benefit Policy Manual (MBPM)* provides that Outpatient Observation Services are a well-defined, specific set of services used to decide a patient's treatment regimen. The services commonly include ongoing short term treatment, assessment, and reassessment before a decision can be made regarding whether patients will require further treatment as hospital inpatients or if they are able to be discharged from the hospital. Observation status is commonly assigned to patients who present to the emergency department and who then require a significant period of treatment or monitoring in order to make a decision concerning their admission or discharge. In most cases, the decision to admit as an inpatient or to discharge can be made within 24 hours. Only in rare and exceptional cases should the observation period last 48 hours or more. All hospital observation services, regardless of the duration of the observation care, that are medically reasonable and necessary are covered by Medicare. The purpose of observation is to determine the need for further treatment or for inpatient admission. Thus, a patient receiving observation services may improve and be released, or be admitted as an inpatient. (*MBPM*, pub. 100-02, Ch. 6, §20.6; *Medicare Claims Processing Manual (MCPM)*, pub. 100-04, Ch. 4, §290.1).

A person is considered a "hospital outpatient" if they have not been admitted by the hospital as an "inpatient", but are registered on the hospital records as an "outpatient" and receives services (rather than supplies alone) from the hospital or CAH (*MBPM*, pub. 100-02, Ch. 6, §20.2). A service is "diagnostic" if it is an examination or procedure to which the patient is subjected, or which is performed on materials derived from a hospital outpatient, to obtain information to aid in the assessment of a medical condition or the identification of a disease. Among these examinations and tests are diagnostic laboratory services such as hematology and chemistry, diagnostic x-rays, isotope studies, EKGs, pulmonary function studies, thyroid function tests, psychological tests, and other tests given to determine the nature and severity of an ailment or injury (*MBPM*, pub. 100-02, Ch. 6, §20.4.1).

While outpatient observation services can last for 48 hours; the true limit that is used and suggested appears to be the 24 hour limitation. By 24 hours, many authorities suggest a decision

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to either admit the patient for further observation/treatment or to discharge the patient should be able to be made (*MBPM*, pub. 100-02, Ch. 6, §20.6; *MCPM*, pub. 100-04, Ch. 4, §290.1 & Ch. 12, §30.6.8-§30.6.9.2).

CMS's Hospital Guidelines for Outpatient Observation Services states:

> "Outpatient Observation is for: Evaluating a patient for possible inpatient admission; Treating patients expected to be stabilized and released in 24 hours (With appropriate documentation, patients can stay in observation more than 24 hours.); Extended recovery following a complication of an outpatient procedure (e.g., abnormal postoperative bleeding, poor pain control, intractable vomiting, delayed recovery from anesthesia). Outpatient Observation is NOT: A substitute for an inpatient admission; For continuous monitoring...." (Exhs. 1-2; CMS Medical Director's Corner, Hospital Guidelines for Outpatient Observation Services (CMS GUIDELINES), by Richard K. Baer MD, Medical Director, Medicare Part A; See link, last viewed 02/03/12, at http://myedutrax2.com/docs/CMS_observation_services.pdf).

There is an *LCD*, *LCD L27548* addressing Acute Care: Inpatient, Observation and Treatment Room Services, which provides:

> The determination of an inpatient or outpatient status for any given patient is specifically reserved to the admitting physician. The decision must be based on the physician's expectation of the care that the patient will require. The general rule is that the physician should order an inpatient admission for patients who are expected to need hospital care for 24 hours or longer and treat other patients on an outpatient basis. An inpatient admission is not covered when the care can be provided in a less intensive setting without significantly and indirectly threatening the patient's safety or health. Although in many institutions there is no difference between the actual medical services provided in inpatient and outpatient observation settings, in such cases the designation still serves to assign patients to an appropriate billing category.
>
> A person is considered an inpatient if he is formally admitted based on the physician's expectation of a need for an appropriate inpatient stay. If the patient dies, is transferred, leaves AMA or recovers in a shorter period of time, an inpatient admission is still appropriate. The justification for the admission, then, is based on the information available at the time of admission. Subsequent information may support a physician's "hunch" that the patient needed inpatient care, but never serves to refute that original determination.
>
> When the admitting physician orders observation services, the patient is considered an outpatient. While specific medical necessity for both inpatient admissions and outpatient observation is always determined on a case-by-case basis, certain diagnoses and procedures generally do not support an inpatient admission, and fall within the definitions of outpatient observation.
>
> Uncomplicated presentations of chest pain (rule out MI), mild asthma/COPD, mild CHF, syncope and decreased responsiveness, atrial arrhythmias and renal colic are all frequently associated with the expectation of a brief (less than 24-

[redacted]

hour) stay unless serious pathology is uncovered. Routine diagnostic cardiac catheterization, electrophysiologic mapping, and renal dialysis are usually performed with a similar short stay expectation and are thus usually outpatient procedures *(LCD L27548).*

The *Medicare Program Integrity Manual (MPIM)* addresses screening tools used to review Medicare claims and provides:

> 6.5.1 - Screening Instruments: The reviewer shall use a screening tool as part of their medical review of acute IPPS and LTCH claims. CMS does not require that you use a specific criteria set. In all cases, in addition to screening instruments, the reviewer applies his/her own clinical judgment to make a medical review determination based on the documentation in the medical record.
>
> The following shall be utilized as applicable, for each case: Admission criteria; Invasive procedure criteria; CMS coverage guidelines; Published CMS criteria; DRG validation guidelines; Coding guidelines; and Other screens, criteria, and guidelines (e.g., practice guidelines that are well accepted by the medical community) Contractors shall consult with physician or other specialists if necessary to make an informed medical review determination. (*MPIM,* pub. 100-08, Ch. 6, §6.5.1).

On July 13, 2012 CMS issued *Technical Direction Letter (TDL) No.: 12309* which provides for the adjustment of hospital admission claims when the claims were initially submitted as inpatient Part A claims which are denied coverage at that level (Part A inpatient) and the claim is to be paid as a Part B outpatient observation level of hospital admission (See link, last viewed 10/18/12 at http://www.wachler.com/files/cms_memorandum_re_effectuating_part_b_reimbursement.pdf) .

On March 13, 2013, the Centers for Medicare & Medicaid Services (CMS) issued *Ruling 1455-R.* The Ruling addresses a hospital's Medicare Part B billing options when a Medicare Part A claim was submitted. The Ruling essentially provides that if a Part A claim is submitted, the Part A claim is all that may be ruled on; and a Part A claim may not be denied but ruled on as favorable as a Part B claim. If no Part B claim was submitted by the hospital, there is no appealable initial determination on Part B services. If the Part A claims are withdrawn there are limited Part B claims which may be considered (See link, last viewed 03/22/13 at http://www.hhs.gov/omha/Data/cmsruling.html).

The *Medicare Benefit Policy Manual (MBPM),* pub. 100-02, Ch. 6, §20.6 addresses Hospital Outpatient Observation Services and provides:

> When a physician orders that a patient receive observation care, the patient's status is that of an outpatient. The purpose of observation is to determine the need for further treatment or for inpatient admission. Thus, a patient receiving observation services may improve and be released, or be admitted as an inpatient (see Pub. 100-02, Medicare Benefit Policy Manual, Chapter 1, Section 10 "Covered Inpatient Hospital Services Covered Under Part A" at http://www.cms.hhs.gov/manuals/Downloads/bp102c01.pdf). For more information on correct reporting of observation services, see Pub. 100-04, Medicare Claims Processing Manual, chapter 4, section 290.2.2.) All hospital observation services,

regardless of the duration of the observation care, that are medically reasonable and necessary are covered by Medicare *(MBPM*, pub. 100-02, Ch. 6, §10, §20.6).

Overpayments are discussed in the *Medicare Financial Management Manual (MFMM)* which provides:

> Overpayments are Medicare payments a provider or beneficiary has received in excess of amounts due and payable under the statute and regulations. Once a determination of an overpayment has been made, the amount is a debt owed by the debtor to the United States Government.
>
> ...
>
> The Federal Claims Collection Act requires timely and aggressive efforts to recover overpayments, including efforts to locate the debtor where necessary, demands for repayment, and establishment of repayment schedules, suspension of interim payments by intermediaries to institutional providers, and recoupment or setoff, where appropriate. (*Medicare Financial Management Manual (MFMM)*, pub. 100-06, Ch. 3, §10).

The *MCPM* provides a Provider will be responsible for non-covered services if the Provider knew or should have known the services would not be covered. A provider may be able to limit the liability or shift liability with Advanced Beneficiary Notices (ABNs) or similar documents. Beneficiaries remain liable for services that are denied as technical or categorical denials, because the service may not meet the definition of a Medicare covered benefit; regardless of the presence of an ABN or not (42 C.F.R.§411.406; *MCPM*, pub. 100-04, Ch. 30, §30.2.1 & §40.1.2).

Analysis

Appellant has provided additional documents with the RFH. To the extent these documents are duplicates or summaries of previously submitted records, like a Position Paper, or they address the issue of good cause for late filing, they are admitted. To the extent the newly submitted records are new evidence they are denied as there has been no showing of good cause (Exhs. 1-2; Exh. 2, pp. 18-19; Exh. 2, pp. 1-32; 42 C.F.R. §405.1028; 42 C.F.R. §405.1018).

The claims at issue include Provider's provision of medical services (Part A Inpatient Hospital Admission) to Beneficiary on DOS [redacted]13, [redacted] to [redacted] 14, [redacted] Any other claims, other than as stated hereinabove, will not be addressed by or ruled on in this decision, as they are not properly before the undersigned (Exhs. 1-2; Exh. 2, pp. 20-26; Exh. 2, pp. 6-11; Exh. 2, pp. 1-4; 42 C.F.R. §405.1032).

This is a de novo review and decision. The undersigned is not bound by the prior decisions. However, the prior decisions are a useful reference point as to how the appeal developed. The Carrier denied the claims stating the records do not show why the services (Part A Inpatient Hospital Admission) could not have been safely provided in another setting (e.g. observation status or as an outpatient). The QIC denied the claim with similar reasoning (Exhs. 1-2; Exh. 2, pp. 20-26; Exh. 2, pp. 6-11). Coverage of the claims at issue, and liability if applicable, will be examined and discussed below.

> "An **inpatient** is a person who has been admitted to a hospital for bed occupancy for purposes of receiving inpatient hospital services. Generally, a patient is considered an inpatient if formally admitted as inpatient with the expectation that

[redacted]

he or she will remain at least overnight and occupy a bed even though it later develops that the patient can be discharged or transferred to another hospital and not actually use a hospital bed overnight....The decision to admit a patient is a complex medical judgment which can be made only after the physician has considered a number of factors, including the patient's medical history and current medical needs, the types of facilities available to inpatients and to outpatients, the hospital's by-laws and admissions policies, and the relative appropriateness of treatment in each setting. Factors to be considered when making the decision to admit include such things as: (1) The severity of the signs and symptoms exhibited by the patient; (2) The medical predictability of something adverse happening to the patient; (3) The need for diagnostic studies that appropriately are outpatient services (i.e., their performance does not ordinarily require the patient to remain at the hospital for 24 hours or more) to assist in assessing whether the patient should be admitted; and (4) The availability of diagnostic procedures at the time when and at the location where the patient presents." (*MBPM*, pub. 100-02, Ch. 1, §10).

Reviewing the factors set forth above, admission was appropriate because: (1) These signs and symptoms were severe, suggesting admission was appropriate. Beneficiary was admitted as an inpatient for IV Hydration, Pain Management, and Blood Transfusions (scheduled to receive 2 units on [redacted], or some combination of them with severe signs and symptoms of: (e.g. 66 year old [redacted] presented to ER complaining of Shortness of Breath (SOB) and Fatigue; ER tests showed: Hypotensive (80/40); Febrile (WBC count 16,000); Past medical history includes: Recurrent [redacted] Cancer with Multiple Metastases (including to the liver); Asthma; Last Chemotherapy was [redacted] (needed IV hydration the day before for volume depletion and anemia); admitted for IV Hydration, Pain Management, and to receive Blood Transfusions (scheduled to receive 2 units on [redacted]). These were severe signs and symptoms; (2) The medical predictability of adverse consequences happening. Beneficiary was admitted with symptoms that suggested adverse consequences (e.g. 66 year old [redacted] presented to ER complaining of Shortness of Breath (SOB) and Fatigue; ER tests showed: Hypotensive (80/40); Febrile (WBC count 16,000); Past medical history includes: Recurrent [redacted] Cancer with Multiple Metastases (including to the liver); Asthma; Last Chemotherapy was [redacted] (needed IV hydration the day before for volume depletion and anemia); admitted for IV Hydration, Pain Management, and to receive Blood Transfusions (scheduled to receive 2 units on [redacted]). Coupled with Beneficiary's age and medical history, the probability of something adverse happening had Beneficiary not received proper medical care promptly was good for an adverse event to occur. Beneficiary had high risk level for complications, serious injury or death; (3) The need for diagnostic studies that appropriately are outpatient services (i.e., their performance does not ordinarily require the patient to remain at the hospital for 24 hours or more) to assist in assessing whether the patient should be admitted: This Beneficiary should not have been treated and tested as an outpatient. Beneficiary needed diagnosed and the acute problem(s) brought under control. Then Beneficiary would need intense close monitoring of Beneficiary's potentially changing conditions and reactions to any attempted treatments. Monitoring would help them adjust Beneficiary's medications and follow Beneficiary's recovery while in the hospital. Admitting Beneficiary as an inpatient provided the intense concentrated services to make complex decisions about treatments as quickly as possible. Inpatient services were exactly what Beneficiary needed. This suggested the problem will not be resolved within 24 hours, so conducting the tests on an observation level admission is not appropriate. Appellant argues the admission was entirely appropriate and medically reasonable and necessary because Beneficiary required closer monitoring in a setting that would provide access to emergent

[redacted]

intervention if necessary; (4) The availability of diagnostic procedures at the time when and at the location where the patient presents: The ER and the observation status rooms do not have the availability of all of the equipment to test and continue to monitor all of Beneficiary's systems with the ease that an inpatient admission to the hospital would provide, nor is the observation unit staffed with nurses having as much higher training and certifications. The telemetry unit is staffed by nurses trained to watch critical care patients, has a smaller staff to patient ratio, and has more specialized equipment more readily available than other units of the hospital. Again, Appellant states the admission afforded this Beneficiary the required closer monitoring in a setting that would provide access to emergent intervention if necessary. These factors all suggest the inpatient admission was medically reasonable and necessary and at the level claimed by Appellant (Exhs. 1-2; Exh. 1, pp. 1-101; Exh. 2, pp. 18-19; Exh. 2, p. 31; *MBPM*, pub. 100-02, Ch. 1, §10).

The QIC suggested a lesser level of care would have worked, such as an observation only status admission. There are several flaws with this option.

First, if one does no not admit Beneficiary but uses outpatient observation status to treat, then one runs into the limitation that outpatient observation status is to be used for 24 hours in order to decide if the person needs to be admitted or if the problem has resolved itself. If the problem does not resolve itself in 24 hours, then the person is usually admitted as an inpatient. Beneficiary was being admitted for suspected ACS, TIA/Stroke or Systemic Problem(s), or some combination of them with complicating factors (i.e. age, medical history and clinical presentation). Predicting this to be resolved in less than 24 hours was anything but a sure thing.

Second, using outpatient observation here would have been contrary to CMS Guidelines for Outpatient Observation Services, which states outpatient observation services are for three (3) situations, none of which was present here. CMS GUIDELINES provides outpatient observation services are appropriate for: (1) Evaluating a patient for possible inpatient admission; (2) Treating patients expected to be stabilized and released in 24 hours (With appropriate documentation, patients can stay in observation more than 24 hours.); (3) Extended recovery following a complication of an outpatient procedure (e.g., abnormal postoperative bleeding, poor pain control, intractable vomiting, delayed recovery from anesthesia). None of these three situations was what Beneficiary presented because: (1) the urgency of Beneficiary's symptoms suggested admission was appropriate; (2) Beneficiary was not expected to be stabilized within 24 hours; (3) Beneficiary was not recovering from any procedure; rather Beneficiary needed stabilized and treatment of the acute medical problem(s) because of Beneficiary's medical condition, as Beneficiary was admitted for IV Hydration, Pain Management, and Blood Transfusions (scheduled to receive 2 units on [redacted] or some combination of them with complicating factors: (e.g. 66 year old [redacted] presented to ER complaining of Shortness of Breath (SOB) and Fatigue; ER tests showed: Hypotensive (80/40); Febrile (WBC count 16,000); Past medical history includes: Recurrent [redacted] Cancer with Multiple Metastases (including to the liver); Asthma; Last Chemotherapy was [redacted] (needed IV hydration the day before for volume depletion and anemia); admitted for IV Hydration, Pain Management, and to receive Blood Transfusions (scheduled to receive 2 units on [redacted]). This required urgent treatment and inpatient hospital admission to isolate the reason(s) for the suspected ACS, TIA/Stroke or Systemic Problem(s), or some combination of them with severe signs and symptoms; then treat the causes and the symptoms. The physicians were anticipating what complications would arise and what additional procedures Beneficiary would need as the physicians tried to resolve this problem. Therefore, Beneficiary was more appropriately admitted and treated as an inpatient (Exhs. 1-2; Exh. 1, pp. 1-101; Exh. 2, pp. 18-19; Exh. 2, p. 31; CMS

[redacted]

GUIDELINES, See link, last viewed 08/17/12, at http://myedutrax2.com/docs/CMS_observation_services.pdf).

Finally, this admission should be covered under the *LCD* because this Beneficiary was not experiencing:

> Uncomplicated presentations of chest pain (rule out MI), mild asthma/COPD, mild CHF, syncope and decreased responsiveness, atrial arrhythmias and renal colic are all frequently associated with the expectation of a brief (less than 24-hour) stay unless serious pathology is uncovered. Routine diagnostic cardiac catheterization, electrophysiologic mapping, and renal dialysis are usually performed with a similar short stay expectation and are thus usually outpatient procedures (Exhs. 1-2; Exh. 1, pp. 1-101; Exh. 2, pp. 18-19; Exh. 2, pp. 1-4; Exh. 2, p. 31; Exh. 5; *LCD L27548*).

This Beneficiary presented for IV Hydration, Pain Management, and Blood Transfusions (scheduled to receive 2 units on [redacted]/14/[redacted]), or some combination of them with complicating factors: (e.g. 66 year old [redacted] presented to ER complaining of Shortness of Breath (SOB) and Fatigue; ER tests showed: Hypotensive (80/40); Febrile (WBC count 16,000); Past medical histnry includes: Recurrent [redacted] Cancer with Multiple Metastases (including to the liver); Asthma; Last Chemotherapy was [redacted]/06/[redacted] (needed IV hydration the day before fnr volume depletion and anemia); admitted for IV Hydration, Pain Management, and to receive Blood Transfusions (scheduled to receive 2 units on [redacted]/14/[redacted]). This was not anticipated to be an uncomplicated diagnostic admission with no need for complex care required. Rather, this was anticipated to be complicated and risky for this Beneficiary. That the physicians reacted to the complications that arose, managed the co-morbidities and managed to safely discharge the Beneficiary after such a brief stay shnuld be to their credit for a job well done. This is compliance with nr substantial deference to the *LCD* (Exhs. 1-2; Exh. 1, pp. 1-101; Exh. 2, pp. 18-19; Exh. 2, pp. 1-4; *LCD L27548*). For all of the above reasons, the undersigned finds admitting Beneficiary as an inpatient (Part A Inpatient Hospital Admission) was medically reasonable and necessary. As to the DRG claimed, Appellant's inpatient admission of Beneficiary was correct on these DOS, so Appellant's claims should be covered as claimed; including the claimed DRG (Exhs. 1-2).

ALJs are bound to follow statutes, regulations and *NCDs*. ALJs give substantial deference to *LMRPs, LCDs* and Medicare Manuals. InterQual is not sanctioned or officially recognized as authoritative by CMS. InterQual and its use is nnt sanctioned in a statute, regulation or *NCD*, a *LMRP, LCD* or part of the Medicare Manual series. The undersigned is required to give InterQual no weight at all. (Exhs. 1-2; §1871(a)(2) of the Act, 42 USCA §1395hh; 42 C.F.R. §405.860; 42 C.F.R. §405.1062; Shalala v. Guernsey Memorial Hospital, 514 U.S. 87, 102 (1995); 71 Fed. Reg. §51050 - §51085, at §51061 (08/28/2006)). The undersigned finds the services are covered by Medicare and liability is now moot (Exhs. 1-2).

[redacted]

Conclusions of Law

The undersigned finds the claims for medical services (Medicare Part A Inpatient Hospital Admission) provided by Appellant Rutland Regional Medical Center to Beneficiary [redacted] for DOS [redacted] 13, [redacted] to [redacted] 14, [redacted] are covered and reimbursable under the Act and its implementing regulations at the DRG and level claimed by Appellant (Part A Inpatient Hospital Admission). The undersigned concludes as a matter of law, these services were medically reasonable and necessary under §1861, §1862 of the Act and documentation requirements of §1833(e) have been satisfied (Exhs. 1-2; §1861(s)(2)(B)(C), §1833(e) of the Act). The undersigned having found Medicare coverage applies to all claims herein and concludes liability is no longer at issue.

Order

The Medicare Contractor is DIRECTED to process the claim in accordance with this decision.

Dated: JUN 2 5 2013

James S. O'Leary
U.S. Administrative Law Judge

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN HOSPITAL ASSOCIATION, *et al.*, Plaintiffs, v. SYLVIA M. BURWELL, in her official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES,[1] Defendant.	Civil Action No. 14-cv-00851 (JEB)

DEFENDANT'S MOTION TO DISMISS FOR LACK OF JURISDICTION

Defendant Sylvia M. Burwell, Secretary of Health and Human Services, by and through undersigned counsel, hereby moves for dismissal of the Complaint pursuant to Rule 12(b)(1) of the Federal Rules of Civil Procedure. In support of this motion, Defendant submits: the accompanying Memorandum of Points and Authorities, which also opposes Plaintiffs' Motion for Summary Judgment; Declaration of Nancy J. Griswold and exhibits thereto; Declaration of Constance B. Tobias and exhibit thereto; and proposed Order.

[1] Pursuant to Fed. R. Civ. P. 25(d), Sylvia M. Burwell, the current Secretary of Health and Human Services, is automatically substituted as the named defendant for Kathleen Sebelius, the former Secretary of Health and Human Services.

Respectfully submitted this 11th day of September, 2014.

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN HOSPITAL ASSOCIATION, *et al.*, Plaintiffs, v. SYLVIA M. BURWELL, in her official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES,[1] Defendant.	Civil Action No. 14-cv-00851 (JEB)

DECLARATION OF NANCY J. GRISWOLD

I, Nancy J. Griswold, declare as follows:

1. I am the Chief Administrative Law Judge for the Office of Medicare Hearings and Appeals (OMHA) within the Department of Health and Human Services (HHS), which, organizationally, is located within the Office of the Secretary. I have held this position since March 1, 2010. Among my duties, I oversee the third level of administrative review for individual Medicare claim and entitlement appeals within HHS, which is also known as the Administrative Law Judge (ALJ) level of review. The statements made in this declaration are based on my personal knowledge, information contained in agency files, and information furnished to me in the course of my official duties.

2. On July 10, 2014, I submitted a written statement on OMHA workloads before the United States House Committee on Oversight & Government Reform Subcommittee on Energy Policy, Health Care & Entitlements, and I read that statement into the record under oath.

[1] Pursuant to Fed. R. Civ. P. 25(d), Sylvia M. Burwell, the current Secretary of Health and Human Services, is automatically substituted as the named defendant for Kathleen Sebelius, the former Secretary of Health and Human Services.

A true and correct copy of that written statement is attached as Exhibit 1. *See also* http://www.hhs.gov/asl/testify/2014/07/t20140710a.html. To the best of my knowledge, the information contained in that written statement continues to be true and accurate.

3. OMHA requires significant additional funding to procure the resources needed to meet the 90-day timeframe for issuing ALJ decisions for all appeals. OMHA has a fixed amount of resources and must set priorities for how it will utilize those limited resources in light of the unprecedented number of appeals that are currently pending, and that continue to be filed, at the ALJ-level of administrative review.

4. Attached as Exhibit 2 is a true and correct copy of a December 24, 2013 letter I sent to appellants who had a significant number of Medicare appeals pending at the ALJ-level of administrative review.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

Executed this 11th day of September, 2014, in Alexandria, Virginia.

Nancy J. Griswold

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN HOSPITAL ASSOCIATION, *et al.*, Plaintiffs, v. SYLVIA M. BURWELL, in her official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES,[1] Defendant.	Civil Action No. 14-cv-00851 (JEB)

DECLARATION OF CONSTANCE B. TOBIAS

I, Constance B. Tobias, declare as follows:

1. I am the Chair of the Departmental Appeals Board (DAB) within the Department of Health and Human Services (HHS), which, organizationally, is located within the Office of the Secretary. I have held this position since April 29, 2007. Among my duties, I oversee the operations of the DAB, including the Medicare Appeals Council (Appeals Council) and the Administrative Appeals Judges (AAJs) that make up the Appeals Council, which provides the fourth and final level of administrative review for individual Medicare claim and entitlement appeals within HHS. The statements made in this declaration are based on my personal knowledge, information contained in agency files, and information furnished to me in the course of my official duties.

2. The Medicare Operations Division of the DAB provides staff support to the Appeals Council. Members of the Appeals Council issue decisions collectively as an

[1] Pursuant to Fed. R. Civ. P. 25(d), Sylvia M. Burwell, the current Secretary of Health and Human Services, is automatically substituted as the named defendant for Kathleen Sebelius, the former Secretary of Health and Human Services.

adjudicative body. There are four AAJs appointed to serve on the Appeals Council. In addition, Departmental Appeals Board members may also issue Appeals Council decisions. I have designated two senior attorneys within the Medicare Operations Division to act as Appeals Officers, through a delegation of authority, and authorized them to issue dispositive orders in certain matters pending before the Appeals Council. Board members and Appeals Officers act on only a very small percentage of the cases reviewed by the Appeals council. AAJs, Board members and Appeals Officers do not exercise the judicial independence of an Administrative Law Judge, and act only on behalf of the Appeal Council, rather than in their individual capacities.

3. On February 12, 2014, I presented the DAB update regarding the status of appeals pending before the Appeals Council at the Office of Medicare Hearings and Appeals (OMHA) Medicare Appellant Forum. A true and correct copy of the document used during that presentation is attached as Exhibit 1 (DAB Presentation). *See also* http://www.hhs.gov/omha/omha_medicare_appellant_forum_presentations.pdf, at 102-120. To the best of my knowledge, the information contained in the DAB Presentation continues to be true and accurate with the following updates. Since February, with the additional processing of fiscal year 2013 appeals, the size of the DAB case backlog at the end of fiscal year 2013 was 5,108 cases, rather than the 4,888 our records reflected at the time of the DAB Presentation. In addition, the DAB now expects to receive between 4,000 and 5,000 Medicare appeals in fiscal year 2014, rather than the 7,000 appeals projected in February. We have now received more than 100 escalations from OMHA to the Council (there had been 19 as of February), and we have now received seven (7) requests for escalation from the Council to United States District Courts (there had been six (6) as of February).

4. In fiscal year 2010, the DAB received approximately 2,000 Medicare appeals, but in fiscal year 2011, that number grew to approximately 3,000. While that number remained steady through fiscal year 2012, in fiscal year 2013, the DAB received more than 4,000 Medicare appeals, doubling its annual intake from 2010. The increased caseload before the Medicare Appeals Council is due in large part to additional appeals from audits conducted under the recently expanded Recovery Audit Contractor (RAC) program.

5. The DAB staff handling Medicare Appeals increased by four attorneys in 2012. Currently, the DAB's Medicare appeals workload far exceeds the Appeals Council's ability to keep up with the volume of incoming appeals, and thus the Appeals Council is unlikely to meet the 90-day timeframe for issuing decisions in most appeals.

6. The DAB has a fixed amount of resources and must set priorities for how it will utilize those limited resources in light of the unprecedented number of appeals currently before the Appeals Council. If the DAB was directed to devote additional staff to deciding Medicare Appeals, the DAB would be unable to meet statutory and regulatory deadlines in other types of cases pending in its Appellate and Civil Remedies Divisions.

7. The DAB is not aware of an instance where a case escalated from the Administrative Law Judge (ALJ) level of review to the Appeals Council has been appealed to federal district court without action by the Council. The DAB is not aware of an instance where a case has been escalated past both the ALJ and DAB levels of administrative review into federal district court for judicial review (a so-called "double escalation"). The DAB is not aware of an instance where a case has been escalated past the Qualified Independent Contractor (QIC), ALJ, and DAB levels of administrative review into federal district court for judicial review (a so-called "triple escalation").

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

Executed this 11th day of September, 2014, in Washington, District of Columbia.

Constance B. Tobias

Constance B. Tobias

Departmental Appeals Board Update

MEDICARE APPEALS COUNCIL

Constance B. Tobias
Chair
HHS Departmental Appeals Board

Office of Medicare Hearings and Appeals (OMHA) – Medicare Appellant Forum – February 12, 2014 – Washington, D.C.

DEPARTMENTAL APPEALS BOARD (DAB)

The DAB is a 76-person umbrella organization, located within the Office of the Secretary and comprised of:

- Departmental Appeals Board Members
- Civil Remedies Division Administrative Law Judges
- Medicare Appeals Council
- Alternative Dispute Resolution Division

MEDICARE APPEALS COUNCIL

The Medicare Appeals Council (Council) is comprised of:

- Board Chair
- Administrative Appeals Judges
- Appeals Officers
- Members of the Departmental Appeals Board (if necessary)

The Council provides the final administrative review for:

- Medicare entitlement
- Fee-for-service claims
- Managed care or prescription drug claims

The Council is supported by the Medicare Operations Division (MOD) attorneys and support staff.

MEDICARE APPEALS COUNCIL: Appeals Process

ALJ Decisions can be appealed by:

- -Provider/Supplier
- -Beneficiary
- -Medicaid State Agency
- -CMS own motion review

Council performs *de novo* review & can take one of the following actions:

- -Adopt
- -Reverse
- -Modify
- -Dismiss
- -Remand

Council decisions can be appealed to federal court IF the amount in controversy is met ($1,430 in 2014)

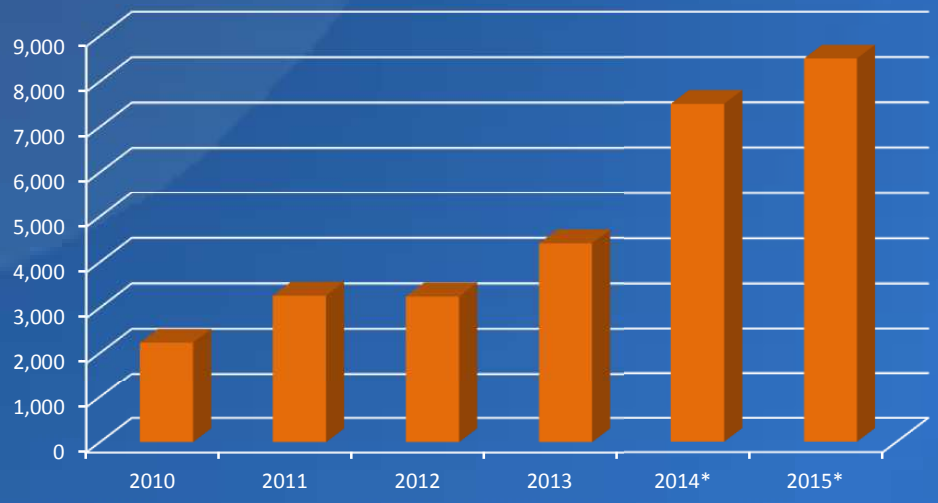
Status of Appeals at the DAB

The number of requests for Council review is steadily increasing:

- In FY 2013, the Council closed 2,592 appeals (13,412 individual beneficiary claims) the largest number in the history of the organization.
- By the end of FY 2013, the number of pending appeals was 4,888. This is 112% more than at the end of FY 2012.

MOD WORKLOAD PROJECTIONS

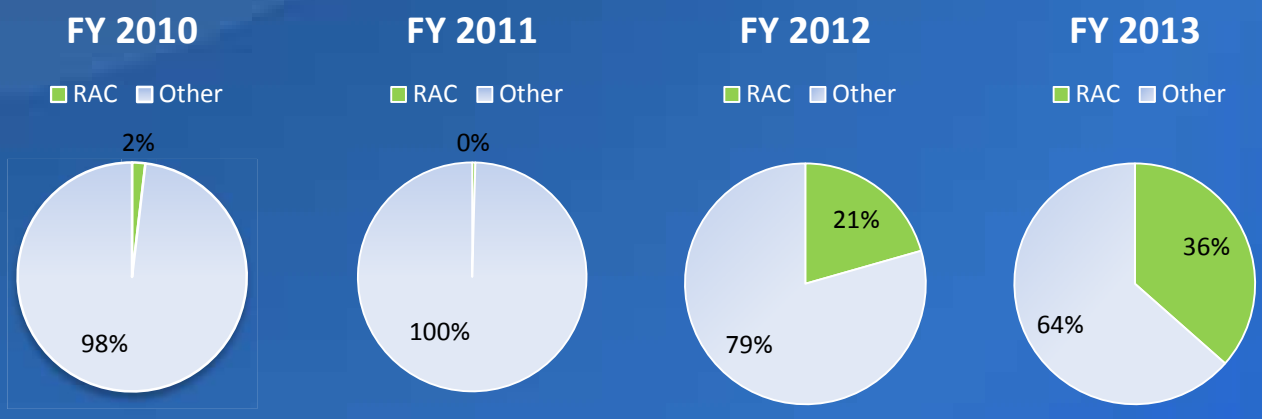
Number of Appeals Received by the Council Per Fiscal Year



**These numbers are based on OMHA workload predictions*

Increase in the MOD Caseload

- Increase in OMHA's case receipts and disposition rates
- Increase in overpayment (including Recovery Audit Contractor) and statistical sampling appeals

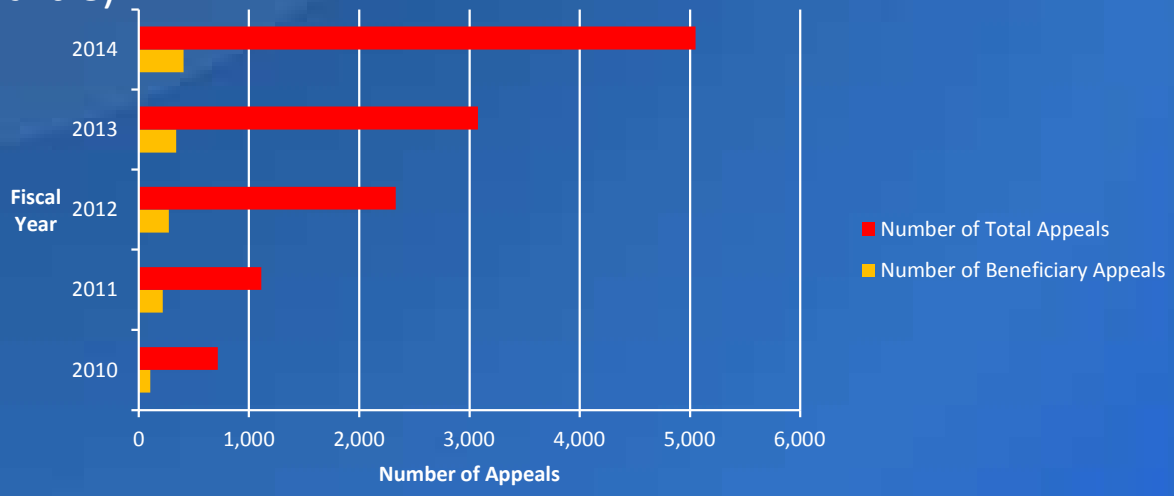


Managing the Increasing Caseload: Council's Actions

- Beneficiary-Focus
- Process Improvement
  - e-Records
  - Appeal consolidation

Beneficiary-Focus

- The Council is unlikely to meet the 90-day deadline for issuing decisions in most appeals
- The Council will give priority to beneficiary appeals (including Part C)



Process Improvements- e-Records

- Pilot program- working with contractors to receive claim files electronically in cases in which CMS seeks own motion review (Agency Referrals)
- Eliminates the work involved with moving/storing paper files, increases the efficiency of document transmittal
- Expanding the use of electronic records to other types of cases, eventually working towards receiving e-records in all cases

Process Improvement- Appeals Consolidation

- Appeals filed by a single appellant with identical issues of law and no significant factual dispute are being consolidated
- The Council will issue one decision in consolidated appeals
- Consolidation will allow the affected appeals to be processed more quickly

Managing the Increasing Caseload: PRACTICE TIPS

- Requests for Review
  - Acknowledgment Letter
- Escalations
  - Escalations from OMHA to the Council
  - Escalations from the Council to Federal Court

PRACTICE TIP:
Follow the instructions in the Council's Acknowledgement Letter

When filing a request for review:

- **CONTENTIONS**: Include an explanation of what part(s) of the ALJ action you disagree with and your reason(s)
- **COPY THE OTHER PARTIES**: Send a copy of the request for review to each party copied by the ALJ. It is not enough to simply send the other parties a letter stating that you have filed an appeal.
- **NEW EVIDENCE**: Notify the other parties of what, if any, supplemental material or new evidence was submitted with the request for review and make it available if requested. Unless instructed otherwise, the Council does not require that you send such documents to each party.

ESCALATIONS

- Escalation requests from OMHA to the Council:
  - In FY 2013, the Council received 7 escalation requests from OMHA to the Council
  - In FY 2014, the Council has already received a total of 19 escalations from OMHA

PRACTICE TIP:
Escalations from OMHA to Council

- Two-Step Process:
  1) The appellant must file a written request for escalation with OMHA. OMHA then issues a decision, dismissal, remand, or a Notice of Escalation Request.
  2) If no action by OMHA within 10 days (including 5 days for mailing time), the appellant can then file a request for escalation with the Council. The appellant must ensure that the request:
     - contains the required content for a request for review of an escalated case as set forth in the regulations;
     - is sent to both the Council and to the ALJ's OMHA office; and
     - is sent to the other parties to the appeal.

42 C.F.R. §§ 405.1104, 405.1106

Review of Cases Escalated from OMHA

- The Council will:
  - NOT hold a hearing or conduct oral argument unless there is an extraordinary question of law/policy/fact
  - Only consider new evidence if the appellant has good cause for submitting it for the first time to the Council
  - Review the QIC's decision *de novo*
  - Take action within 180 calendar days beginning on the date the request for escalation is received by the Council
  - Issue a decision, dismissal, or remand to the ALJ for further proceedings

ESCALATIONS

- Escalation requests from the Council to Federal Court:
  - In FY 2013, there were a total of 2 escalation requests to federal court
  - In FY 2014, the Council has already received 6 escalation requests to federal court

Escalations from the Council to Federal Court

- If the Council has not issued a decision within 90 days from the date it received an appellant's request for review, the appellant may file a request for escalation to federal court in writing to the Council
- After receiving a request for escalation, within 5 calendar days, the Council must:
  - Issue a decision;
  - Issue a dismissal;
  - Remand the case to the ALJ; OR
  - Send notice to the appellant acknowledging receipt of the request to escalate and confirming that it is unable to issue a decision

42 C.F.R. § 405.1132

Escalations from the Council to Federal Court

- If the appellant receives a notice from the Council that no decision will be issued, the appellant may then file an action in federal district court within 60 calendar days

Thank you for your attention.

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

AMERICAN HOSPITAL ASSOCIATION Plaintiff, vs. SYLVIA MATHEWS BURWELL, SECRETARY OF HEALTH AND HUMAN SERVICES Defendant.	)	Case No. 1:14-CV-851-JEB

DECLARATION OF SAMUEL FLEMING

I, Samuel Fleming, declare as follows:

1. I am Director of eRehabData, located at 816 Thayer Ave, Silver Spring, MD. I have held this position since December, 2000. I am the original designer of eRehabData and direct all policy and technological development of the system.

2. eRehabData is a database application offered by the American Medical Rehabilitation Providers Association (AMRPA) to its members. eRehabData provides members with real-time financial and clinical outcomes and benchmarks. eRehabData is a complete online patient assessment system to assist rehabilitation hospitals in their compliance with CMS's regulations under the Medicare inpatient rehabilitation facility prospective payment system. The eRehabData system also tracks Medicare audits and appeals.

3. The audit and appeals information in eRehabData is self-reported by AMRPA members who use the system. The eRehabData system tracks the number and dollar value of Medicare cases at each stage of appeal. The eRehabData system also tracks the outcome at each stage of appeal.

4. On August 26, 2014, I generated the attached report from the eRehabData system. The attached report is a true and accurate representation of the information contained in the eRehabData system as of that date.

I solemnly declare under penalty of perjury that the above statements are true, accurate, and complete, based upon my personal knowledge.

Executed on September 29, 2014 in Silver Spring, Maryland.

9/30/2014

Samuel Fleming Date
Director
eRehabData

Appeals Report

This outcomes result set generated on 08/26/2014 at 10:31 PM EDT

Data Set: Nation
Discharged: 02/27/2005 to 08/26/2014
Compliance: All Assessments
Appeal Status: All Assessments

Follow-Up Calculations:

Total Discharges	1900321	
Medicare Discharges	1208170 (63.58%)	
Medicare Discharges Denied	2858 (0.24%)	
Total Claim Amount	$48,248,641.12	

Active Appeals

	# Discharges	Percentage of Active Appeals	Total Claim Amount	Total Under Dispute	Total Amount Paid
Additional Documentation/Medical Records Request	1029	63.56%	$17,084,789.90	$4,795,627.99	$654,155.43
Redetermination Request (Appeal)	127	7.84%	$2,041,450.33	$2,099,807.07	$13,783.00
Reconsideration Request to QIC	246	15.19%	$3,583,568.30	$3,724,235.48	$0.00
Administrative Law Judge (ALJ) Hearing Request	189	11.67%	$2,836,580.92	$2,834,575.54	$0.00
Medicare Appeals Council (MAC) Request	16	0.99%	$308,586.78	$308,586.78	$0.00
Federal District Court	12	0.74%	$112,904.00	$112,904.00	$0.00
Medicare Discharges Under Appeal	1619	0.13%	$25,967,880.23	$13,875,736.86	$667,938.43

Closed Appeals

	# Discharges	Appeals Upheld	Appeals Denied	Total Claim Amount	Total Amount Denied	Total Amount Paid
Additional Documentation/Medical Records Request	654	599 (91.59%)	55 (8.41%)	$12,395,408.36	$575,305.74	$11,820,102.62
Redetermination Request (Appeal)	134	67 (50%)	67 (50%)	$2,267,522.00	$902,474.00	$1,247,496.84
Reconsideration Request to QIC	162	86 (53.09%)	76 (46.91%)	$2,941,764.75	$1,399,909.29	$1,715,885.97
Administrative Law Judge (ALJ) Hearing Request	283	237 (83.75%)	46 (16.25%)	$4,573,295.88	$635,604.74	$3,927,033.20
Medicare Appeals Council (MAC) Request	6	1 (16.67%)	5 (83.33%)	$102,769.91	$88,603.05	$14,166.86
Federal District Court	0	0 (0%)	0 (0%)	$0.00	$0.00	$0.00
Totals	1239	990	249	$22,280,760.89	$3,601,896.81	$18,724,685.49

** Discharge avgs have been recalculated for only those assessments with Follow-Up data.

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

AMERICAN HOSPITAL ASSOCIATION Plaintiff, vs. SYLVIA MATHEWS BURWELL, SECRETARY OF HEALTH AND HUMAN SERVICES Defendant.	)	Case No. 1:14-CV-851-JEB

DECLARATION OF BRIGID GREENBERG

I, Brigid Greenberg, declare as follows:

1. I am Manager of Post Discharge Services and Appeals and Business Development Advisor for Uniform Data System for Medical Rehabilitation ("UDSMR"), located at 270 Northpointe Parkway, Suite 300, Amherst, New York 14228. I have held this position since May 2014. I am responsible for leading Appeals Services, including consulting, educating and representing IRF's in their Medicare Appeal activities.

2. UDSMR is a not-for-profit organization affiliated with the University at Buffalo, The State University of New York. Since its inception in 1987, UDSMR has provided comprehensive rehabilitation data to the industry. CMS has adopted UDSmr's FIM® instrument for the IRF prospective payment system.

3. UDSMR maintains a large database for medical rehabilitation outcomes. UDSMR also manages Medicare audits and appeals for 36 rehabilitation hospitals. The audit and appeals information in UDSMR's database is information tracked for these hospitals.. UDSMR tracks the number and dollar value of Medicare cases at each stage of appeal. UDSMR system also tracks the outcome at each stage of appeal.

4. Of the cases tracked by UDSMR that have been heard by ALJs, 85% have been in favor of rehabilitation hospitals. UDSmr's database currently has 547 rehabilitation hospital cases pending at the ALJ level, representing over $9 million in payments to rehabilitation hospitals. Some of these pending appeals were submitted to OMHA as long ago as June 2012.

5. One of UDSMR's most affected clients is a 48-bed facility that has 116 cases pending at the ALJ, representing almost $2 million in Medicare claims. This hospital's cases have been pending at the ALJ level of appeal since October 2012.

I solemnly declare under penalty of perjury that the above statements are true, accurate, and complete, based upon my personal knowledge.

Executed on September 30, 2014 in Lakehills, Texas].

Brigid Greenberg 9-30-14

Brigid Greenberg Date
Manager of Post Discharge Services and Appeals
and Business Development Advisor
Uniform Data System for Medical Rehabilitation

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

AMERICAN HOSPITAL ASSOCIATION Plaintiff, vs. SYLVIA MATHEWS BURWELL, SECRETARY OF HEALTH AND HUMAN SERVICES Defendant.	)	Case No. 1:14-CV-851-JEB

DECLARATION OF DAVID MORONY

I, David V. Morony, declare as follows:

1. I am the Chief Financial Officer at Casa Colina Centers for Rehabilitation ("Casa Colina") located at 255 East Bonita Avenue, Pomona, California. I have held this position since June 18, 2012.

2. Casa Colina operates a 68-bed inpatient rehabilitation facility ("IRF").

3. Casa Colina is a member of the Fund for Access to Inpatient Rehabilitation.

4. Since August 2012, Casa Colina has experienced approximately 159 audits of inpatient claims and an additional 50 audits of outpatient claims.

5. Casa Colina routinely appealed all of the inpatient claim denials that resulted from these audits when it disagreed with the audit findings. To date, Casa Colina has appealed 159 claim denials, with 106 resolved. Of the 53 appeals that remain outstanding, 17 are currently awaiting a hearing before an Administrative Law Judge ("ALJ"). Casa Colina is also in the process of preparing an additional four requests for ALJ hearing that will be submitted shortly.

6. The total monetary value of the 53 claims still under appeal is $1,237,597. Of this amount, $429,395, or 35%, is related to claims pending at the ALJ level of the administrative appeals process. The remaining balance is related to claims still at the lower levels of appeal, which may reach the ALJ level within the next six months.

7. The extended delay in obtaining an ALJ decision on Casa Colina's outstanding appeals has negatively impacted the financial viability of its IRF by impacting its ability to borrow money, in sufficient quantity and at the most favorable terms, for capital needs and implementation of an electronic health record system. Furthermore, Casa Colina is in the midst of a major capital initiative. Because funds are being withheld during the extended appeals process, Casa Colina is forced to borrow additional funds to cover expenses it would otherwise be able to finance itself, without the need to incur interest.

8. In addition, the uncertainty created by the delay in obtaining ALJ decisions has impacted the types of patients admitted by Casa Colina. Without being able to obtain final appeal decisions in a timely fashion, Casa Colina has been forced to avoid admitting certain types of patients, regardless of whether its staff believes the patients meet the coverage criteria for IRF care, if those patients have indicia within their medical records that are likely to be audited such as lower extremity joint replacement or debilitated physical condition following an extended acute care hospital admission. Because of the prolonged appeals process, it is very financially risky for Casa Colina to admit patients who do not have certain medical conditions (e.g., traumatic brain injury or spinal cord injury), even if the patients' conditions would benefit from inpatient rehabilitation services. Therefore, fewer of these patients are admitted to Casa Colina than in the past.

I solemnly declare under penalty of perjury that the above statements are true, accurate, and complete, based upon my personal knowledge.

Executed on September 29, 2014 in Pomona, California.

David V. Morony — Date
Chief Financial Officer
Casa Colina Centers for Rehabilitation

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

AMERICAN HOSPITAL ASSOCIATION Plaintiff, vs. SYLVIA MATHEWS BURWELL, SECRETARY OF HEALTH AND HUMAN SERVICES Defendant.	)	Case No. 1:14-CV-851-JEB

DECLARATION OF GARY ARMSTRONG

I, Gary Armstrong, declare as follows:

1. I am the Executive Vice President and Chief Financial Officer at Methodist Rehabilitation Center ("Methodist") located at 1350 East Woodrow Wilson, Jackson, Mississippi. I have held this position since April 1999. .

2. As part of my job, I routinely track the audits conducted by the Centers for Medicare and Medicaid Services and its contractors and help coordinate Methodist's appeals of any resulting claim denials.

3. Methodist operates as a 93-bed inpatient rehabilitation facility ("IRF").

4. Since April 4, 2012, Methodist has experienced 144 audits or IRF claims, resulting in 72 claim denials.

5. To date, Methodist has appealed all 72 claim denials. Of these appeals, 57 remain pending, with 54 awaiting a hearing before an Administrative Law Judge ("ALJ") and three awaiting a decision from the Qualified Independent Contractor.

6. The total monetary value of the claims appealed is $1,283,636. Of this amount, $912,087, or 71%, is related to claims pending at the ALJ level of the administrative appeals process.

7. Methodist experienced a negative cash flow in fiscal years 2013 and 2014 due to the auditing activity and failure of the administrative appeals process to be completed in a timely fashion. Specifically, Methodist had operations losses of $733,594 in FY 2013 and $433,253 in FY 2014.

8. Methodist has postponed conversion to an electronic health records system. With a large amount of funds tied up in the administrative appeals process and the uncertainty over when those funds will become available, the IRF is not able to devote its financial resources to this type of operations improvement.

9. Due to the financial uncertainty caused by the delay in appeals adjudication, Methodist did not provide pay increases to its staff for 2013 and it is currently evaluating its decision for 2014. This can result in losing highly skilled and experienced staff in a competitive workforce marketplace.

10. Additionally, Methodist has had to add an attorney, part time, to its payroll to help address the administrative appeals process.

11. Within approximately a 90 mile radius of Methodist, there is currently only one other IRF.

I solemnly declare under penalty of perjury that the above statements are true, accurate, and complete, based upon my personal knowledge.

Executed on October 1, 2014 in Jackson, Mississippi.

10-1-2014

Gary Armstrong — Date
Executive Vice President and CFO
Methodist Rehabilitation Center

UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

STEPHEN LESSLER, et al., Plaintiffs, v. SYLVIA MATHEWS BURWELL, Secretary of Health and Human Services, Defendant.	No. 3:14-cv-1230 (JAM)

DECLARATION OF NANCY J. GRISWOLD CHIEF ADMINISTRATIVE LAW JUDGE
OFFICE OF MEDICARE HEARINGS AND APPEALS

I, Nancy J. Griswold, pursuant to the provisions of 28 U.S.C. 1746, declare:

1. My name is Nancy J. Griswold.

2. I am the Chief Administrative Law Judge for the Office of Medicare Hearings and Appeals ("OMHA") at the U.S. Department of Health and Human Services ("HHS").

3. OMHA Administrative Law Judges ("ALJs") issue agency decisions on appeals of, among others, determinations by Qualified Independent Contractors ("QICs") and Quality Improvement Organizations ("QIOs") on claims for benefits under the Medicare fee-for-service program.

4. OMHA, a staff division within the HHS Office of the Secretary, administers the nationwide ALJ hearing program for Medicare claims appeals under 42 U.S.C. §§ 1395ff and 1320c-4. OMHA ensures that Medicare beneficiaries, and the providers and

suppliers that furnish items or services to Medicare beneficiaries, as well as Medicaid State Agencies (MSAs) that have made payment or may be liable for services furnished to beneficiaries who are enrolled in both Medicare and Medicaid, have a fair and impartial forum to address disagreements with Medicare claim determinations.

5. In addition to Part A and Part B claim determination appeals, OMHA is a forum for appeals of Medicare eligibility, entitlement, and income-related premium surcharges made by the Social Security Administration (SSA); organization determinations on coverage made by Medicare Advantage Organizations, health maintenance organizations, and competitive medical plans under 42 U.S.C. §§ 1395mm and 1395w-22; and coverage determinations on prescription drug coverage made by Part D plan sponsors under 42 U.S.C. § 1395w-104.

6. The Medicare claims appeals process for beneficiary claims generally consists of four levels of administrative review within HHS, and a fifth level of review with the federal district courts after administrative remedies within HHS have been exhausted. The first two levels of review are administered by the Centers for Medicare & Medicaid Services (CMS) and conducted by Medicare contractors. The third level of review is administered by OMHA and is conducted by ALJs. Subsequent reviews are conducted at the fourth level of appeal within the Departmental Appeals Board (DAB), and at the fifth level by the federal district courts. See 42 CFR 405.900–405.1140.

7. The Medicare appeals process for a beneficiary's continuation care is somewhat different, generally consisting of three levels of administrative review within HHS, and a fourth level of review with the federal district courts after administrative remedies within HHS have been exhausted. The first level is the reconsideration level conducted by a QIO.

The second level of review is administered by OMHA and is conducted by ALJs. Subsequent reviews are conducted at the third level of appeal within the DAB and at the fourth level by the federal district courts. See 42 CFR 478.10–478.48.

8. HHS established OMHA in June 2005 pursuant to section 931 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173) (MMA) which required the transfer of responsibility for the ALJ hearing function of the Medicare claims and entitlement appeals process from the SSA to HHS. OMHA was established to improve service to appellants and to reduce the average 368-day waiting time for a hearing decision that appellants experienced with SSA to the 90-day time frame for issuing dispositions established in the Medicare, Medicaid, and SCHIP Benefits and Improvement Act of 2000 (BIPA) (Pub. L. 106-554). In order to ensure that OMHA's adjudicators would have decisional independence from CMS, OMHA was established as a separate agency within HHS, reporting directly to the Secretary. Accordingly, OMHA operates under a separate appropriation and is both functionally and fiscally separate from CMS.

9. At the time OMHA was established, Congress envisioned that OMHA would receive appeals of:

> Medicare Part A and Part B claim denials reviewed by a QIC, and Medicare provider discharges that are reviewed by a QIO;
>
> Medicare Advantage Organization (Part C) determinations reviewed by an independent review entity or a QIO;
>
> Prescription Drug Plan Sponsor (Part D) coverage determinations reviewed by an independent review entity; and

Medicare entitlement and premium determinations reconsidered by SSA.

10. With this mix of work at the expected levels, OMHA was for the most part able to meet the 90-day time frame that Congress contemplated appeals of Medicare Part A and Part B QIC reconsiderations. However, starting in FY 2010, OMHA began to experience an upward trend in the number of requests for hearings and delays in the average processing times for appeals.

11. From FY 2011 thru FY 2013, the upward trend in receipt levels took an unexpectedly sharp turn and OMHA experienced an overall 545% growth in appeals (from 59,600 in FY 2011 to 384,151 in FY 2013). This rise in the number of appeals resulted both from increases in the number of beneficiaries utilizing services covered by Medicare (CMS now processes more than one billion claims annually) and from increased auditing activity to protect the Medicare Trust Funds, including the nationwide implementation of the Recovery Audit Program in 2010. The Recovery Audit Program, established by Congress, has been very successful, returning billions of dollars in improper payments to the Medicare Trust Fund. There have also been increases in MSA appeals of Medicare coverage denials for beneficiaries enrolled in both Medicaid and Medicare, when the MSA has made payment or is liable for the services if they are not covered by Medicare. Although ALJ productivity (dispositions per ALJ) more than doubled from FY 2009 through FY 2013 (from an average of 534 dispositions per year in FY 2009, to 1260 in FY 2013), the magnitude of these increases in appeals has exceeded OMHA's ability to adjudicate incoming appeals within the 90-day time frame that Congress contemplated for appeals of Medicare Part A and Part B QIC reconsiderations. As a result of the

significant disparity between workload and capacity, adjudication time frames have increased to an overall average of 407 days in FY14 (as of August 31, 2014).

12. Recognizing that increasing time frames to obtain a decision could have significant implications on the most vulnerable appellant population that OMHA serves, Medicare beneficiaries, OMHA began prioritizing the processing of beneficiary appeals in July 2013, and established a mail-stop for beneficiary-specific appeals in February 2014, to ensure they are quickly identified and assigned to an ALJ for hearing. These measures have resulted in an average processing time of 109 days for requests filed by beneficiaries in FY2014, according to data available in the Medicare Appeals System (MAS), the OMHA case management and tracking system, as of October 1, 2014.

13. In addition to these measures for beneficiary appeals, OMHA has been able to maximize its productivity overall by supporting each of its ALJs with assigned processing teams consisting of attorneys and other support staff. This has allowed each ALJ to focus on hearing and deciding appeals functions that can only be performed by ALJs. However, OMHA's adjudication capacity is ultimately limited by the number of ALJs and support staff (ALJ teams). Under the 2014 continuing resolution, OMHA's funding level supported 65 ALJ teams. OMHA's 2014 enacted funding level allowed for the hiring of 7 additional ALJ teams, who reported for duty on August 25, 2014. This brings OMHA's adjudication capacity to approximately 72,000 appeals per year. However, this capacity pales in comparison to the adjudication workload. In FY 2013 alone, OMHA received 384,151 appeals, and in FY 2014, OMHA had received approximately 509,124 appeals through July 1, 2014. The number of appeal requests filed each week has ranged between 10,000 and 16,000 throughout FY 2014. As a result, OMHA had over 800,000

appeals pending on July 1, 2014. At current receipt and adjudication capacity levels, OMHA is receiving one year's worth of appeals every four to six weeks.

14. Due to the rapid and persistent influx of appeals, by July 2013, OMHA's field offices faced significant challenges in their ability to safely store the large number of physical files associated with appeals pending hearing, and each ALJ team had an estimated two years' worth of appeals currently assigned to them. As a consequence, with the exception of appeals filed by beneficiaries, OMHA began deferring assignment of requests for hearing to an ALJ, until an ALJ's docket could accommodate the additional work and the team could manage the physical case files. The decision to defer assignment of appeals was a management decision related to the geography of case storage and did not cause any additional delays in the hearing and decision of appeals. In February 2014, OMHA began to assign a limited number of non-beneficiary appeals to ALJs who were able to accommodate additional appeals on their dockets. Throughout this time, OMHA has continued to conduct hearings and issue decisions on appeals already assigned to ALJs.

15. In the face of dramatically increasing workloads, OMHA recognizes the need to deliver high quality and timely decisions on benefits and services to the Medicare community with greater efficiency. OMHA is also pursuing a transition from the current paper adjudication process to a fully electronic process, with the first phase expected in the summer of 2015, and automating notices and routine correspondences to further increase productivity.

16. Recognizing the gravity of its workload challenges, OMHA proposed and former Secretary Sebelius established a departmental interagency workgroup in 2013, which included leaders from each of the three HHS agencies involved in the Medicare appeals

process (CMS, OMHA, and DAB). This interagency group conducted a thorough review of the appeals process and developed a series of initiatives that both OMHA and CMS are implementing to reduce the current backlog of pending appeals and the number of appeals that reach OMHA.

17. As a result of this cross-component cooperation and with the assistance from departmental leaders, OMHA is now implementing a number of pilot programs. To bolster the priority processing of beneficiary appeals, OMHA has redirected the efforts of its senior attorneys to assist the ALJs in adjudicating these appeals. Any beneficiary who believes his or her case is not receiving priority consideration at OMHA may contact OMHA directly by e-mail at Medicare.Appeals@hhs.gov or at OMHA's toll free number, 855-556-8475.

18. The Department is committed to bringing these efforts and the resulting appeal workload into balance. With that goal in mind, OMHA continues to work with departmental leaders to develop comprehensive solutions to address the appeals workload and maximize service to beneficiaries by ensuring their appeals are processed as quickly as possible.

19. [redacted]

[redacted]

20. [redacted]

21. [redacted]

22. Based upon the data available in MAS as of October 1, 2014, there were 2518 beneficiary-initiated appeals pending at the ALJ level. Of those 2518 appeals, 1409 were subject to the statutory 90-day time frame provided for at 42 U.S.C. § 1395ff(d)(1), after which escalation rights are available.

23. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Nancy J. Griswold

NANCY J. GRISWOLD

Executed on October 9, 2014, in Arlington, Virginia.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN HOSPITAL ASSOCIATION, *et al.*, Plaintiffs, v. SYLVIA M. BURWELL, in her official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES, Defendant.	Civil Action No. 14-cv-00851 (JEB)

DECLARATION OF LESTER D. CASH

I, Lester D. Cash, declare as follows:

1. I am the Associate Deputy Assistant Secretary for Budget of the U.S. Department of Health and Human Services (HHS). In this role, I serve in the Office of Budget within the Office of the Assistant Secretary for Financial Resources within HHS. I have held this position since January 2007. Among my duties, I am responsible for certain aspects of Department-wide budget execution. In fiscal year 2014, these responsibilities included assuring that transfers executed under section 206 of division H of the Consolidated Appropriations Act, 2014 (Pub. L. 113-76) were consistent with the authorities provided in that section. The statements made in this declaration are based on my personal knowledge, information contained in agency files, and information furnished to me in the course of my official duties.

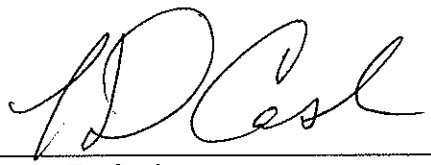
2. Attached as Exhibit 1 is a true and correct copy of a February 21, 2014 letter from former Secretary of Health and Human Services Kathleen Sebelius to the Chairman of the Subcommittee on Labor, Health and Human Services, Education, and Related Agencies of the Committee on Appropriations of the House of Representatives and a true and correct copy of the attachment to that letter. Identical letters and attachments were sent to the Ranking Member of such subcommittee, and to the Chairman and Ranking Member of the Subcommittee on Labor,

Health and Human Services, Education, and Related Agencies of the Committee on Appropriations of the Senate.

3. Attached as Exhibit 2 is a true and correct copy of a May 23, 2014 letter from former Secretary of Health and Human Services Kathleen Sebelius to the Chairman of the Subcommittee on Labor, Health and Human Services, Education, and Related Agencies of the Committee on Appropriations of the House of Representatives and a true and correct copy of the attachment to that letter. Identical letters and attachments were sent to the Ranking Member of such subcommittee, and to the Chairman and Ranking Member of the Subcommittee on Labor, Health and Human Services, Education, and Related Agencies of the Committee on Appropriations of the Senate.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

Executed this 17th day of October, 2014, in Washington, District of Columbia.



Lester D. Cash

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

February 21, 2014

The Honorable Jack Kingston
Chairman
Subcommittee on Labor, Health and
Human Services, Education, and Related Agencies
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

I am writing to inform you that the Department of Health and Human Services (HHS) plans to reallocate $162 million in resources to support activities that are vital to accomplishing the mission of HHS. I am providing this notification consistent with the requirements of section 206 of division H of the Consolidated Appropriations Act, 2014 (P.L. 113-76).

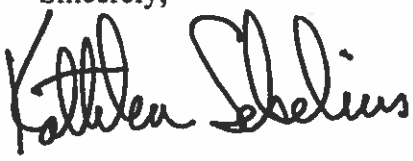
HHS will transfer the funds to two operating divisions to carry out the following activities:

- Centers for Medicare & Medicaid Services (CMS). HHS will transfer approximately $119 million to CMS, of which approximately $109 million will help ensure continued operations of the Marketplace. Even after the open enrollment period ends on March 31, 2014, CMS will continue to provide assistance to consumers to newly enroll in plans and to access their new benefits. CMS will also provide support to issuers in their first year of offering Marketplace plans, as well as plan for 2015 offerings. In addition, HHS will transfer approximately $9 million to CMS to support ongoing information technology maintenance and support.

- Administration for Children and Families (ACF). HHS will transfer approximately $44 million to ACF's Refugee and Entrance Assistance appropriation to care for the increasing number of unaccompanied alien children arriving in the United States. Following eight years of stability, Unaccompanied Alien Children (UAC) arrivals increased 108 percent in fiscal year (FY) 2012, an additional 81 percent in FY 2013, and are projected to increase another 143 percent in FY 2014. ACF has streamlined its placement process, cutting the average amount of time children spend in care in half since FY 2011, and is implementing further cost reductions, but UAC costs continue to rise with the increase in arrivals. Congress has provided an additional $492 million for UAC in FY 2014 but the additional funds and savings are not sufficient to shelter 60,000 UAC arrivals. This transfer is needed to serve ACF's current estimate of the number of arriving UAC without reducing other refugee services.

Enclosed is a table that details the contributions that support the transfers described above. In the current fiscal environment, the use of this transfer authority is necessary to allow HHS to implement the Department's legally mandated responsibilities effectively. I appreciate the Subcommittee's continued interest in and support of the activities of HHS.

Sincerely,



Kathleen Sebelius

Enclosure

Department of Health and Human Services
Fiscal Year 2014 Transfer
(amounts in millions)

Operating Division	Budget Authority	Transfer Out	Transfer In	Revised Level
Health Resources and Services Administration (HRSA):				
Primary Health Care	1,495.276	-3.754	-	1,491.522
Health Workforce	734.236	-1.845	-	732.391
Maternal and Child Heath	846.017	-2.124	-	843.893
Ryan White	2,293.781	-5.757	-	2,288.024
Heath Care Systems	103.193	-0.258	-	102.935
Rural Health	142.335	-0.357	-	141.978
Family Planning	286.479	-0.719	-	285.760
Program Management	153.061	-0.384	-	152.677
HRSA Total		**-15.198**		
Centers for Disease Control and Prevention (CDC):				
Immunization and Respiratory Diseases	611.384	-1.575	-	609.809
HIV/AIDS, Viral Hepatitis, Sexually Transmitted Diseases, and Tuberculosis Prevention	1,120.566	-2.957	-	1,117.609
Emerging and Zoonotic Infectious Diseases	340.814	-0.792	-	340.022
Chronic Disease Prevention and Health Promotion	741.962	-1.961	-	740.001
Birth Defects, Developmental Disabilities, Disabilities and Health	132.337	-0.337	-	132.000
Public Health Scientific Services	397.266	-0.957	-	396.309
Environmental Health	166.811	-0.407	-	166.404
Injury Prevention and Control	150.839	-0.392	-	150.447
National Institute for Occupational Safety and Health	220.860	-0.497	-	220.363
Global Health	414.434	-1.056	-	413.378
Public Health Preparedness and Response	1,371.198	-3.647	-	1,367.551
CDC Total		**-14.578**		
National Institutes of Health (NIH):				
NCI - National Cancer Institute	4,923.238	-12.359	-	4,910.879
NHLBI - National Heart, Lung, and Blood Institute	2,988.605	-7.502	-	2,981.103
NIDCR - National Institute of Dental and Craniofacial Research	398.650	-1.001	-	397.649
NIDDK - National Institute of Diabetes and Digestive and Kidney Diseases	1,744.274	-4.379	-	1,739.895
NINDS - National Institute of Neurological Disorders and Stroke	1,587.982	-3.986	-	1,583.996
NIAID - National Institute of Allergy and Infectious Diseases	4,358.841	-10.942	-	4,347.899
NIGMS - National Institute of General Medical Sciences	2,364.147	-5.935	-	2,358.212
NICHD - Eunice Kennedy Shriver National Institute of Child Health and Human Development	1,282.595	-3.220	-	1,279.375
NEI - National Eye Institute	682.077	-1.712	-	680.365
NIEHS - National Institute of Environmental Health Sciences	665.439	-1.670	-	663.769
NIA - National Institute on Aging	1,171.038	-2.940	-	1,168.098
NIAMS - National Institute of Arthritis and Musculoskeletal and Skin Diseases	520.053	-1.305	-	518.748
NIDCD - National Institute on Deafness and Other Communication Disorders	404.049	-1.014	-	403.035
NINR - National Institute of Nursing Research	140.517	-0.353	-	140.164
NIAAA - National Institute on Alcohol Abuse and Alcoholism	446.025	-1.120	-	444.905
NIDA - National Institute on Drug Abuse	1,025.435	-2.574	-	1,022.861
NIMH - National Institute of Mental Health	1,446.172	-3.630	-	1,442.542
NHGRI - National Human Genome Research Institute	497.813	-1.250	-	496.563
NIBIB - National Institute of Biomedical Imaging and Bioengineering	329.172	-0.826	-	328.346
NCCAM - National Center for Complementary and Alternative Medicine	124.296	-0.312	-	123.984
NIMHD - National Institute on Minority Health and Health Disparities	268.322	-0.674	-	267.648
FIC - John E. Fogarty International Center	67.577	-0.169	-	67.408
NLM - National Library of Medicine	327.723	-0.823	-	326.900
NCATS - National Center for Advancing Translational Sciences	633.267	-1.590	-	631.677
OD - Office of the Director	1,400.134	-3.515	-	1,396.619
B&F - Buildings and Facilities	128.663	-0.322	-	128.341
NIH Total		**-75.123**		
Substance Abuse and Mental Health Services Administration (SAMHSA):				
Mental Health	1,055.347	-2.634	-	1,052.713
Substance Abuse Treatment	2,052.661	-5.181	-	2,047.480
Substance Abuse Prevention	175.631	-0.431	-	175.200
Health Surveillance and Program Support	151.296	-0.377	-	150.919
SAMHSA Total		**-8.623**		
Centers for Medicare & Medicaid Services (CMS):				
Program Management	3,647.740	-	+109.432	3,757.172
Sec. 222 Medicare Program	305.000	-	+9.150	314.150
CMS Total	**3,952.740**	**-**	**+118.582**	**4,071.322**
Administration for Children and Families (ACF):				
Low Income Home Energy Assistance	3,424.549	-34.245	-	3,390.304
Refugee and Entrant Assistance	1,486.095	-	+43.848	1,529.943
Children and Families Services Programs	10,346.943	-6.400	-	10,340.543
ACF Total		**-40.645**	**+43.848**	
Administration for Community Living (ACL)	**1,662.258**	**-4.042**	**-**	**1,658.216**
Office of the Secretary (OS):				
General Departmental Management	458.056	-1.247	-	456.809
Office of the National Coordinator for Health Information Technology	15.556	-0.039	-	15.517
Public Health and Social Services Emergency Fund	1,243.430	-2.935	-	1,240.495
OS Total		**-4.221**		
Department of Health and Human Services Total		**-162.430**	**+162.430**	

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

May 23, 2014

The Honorable Jack Kingston
Chairman
Subcommittee on Labor, Health and
Human Services, Education, and Related Agencies
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

I am writing to inform you that the Department of Health and Human Services (HHS) plans to transfer $12.7 million in fiscal year (FY) 2014 resources using the one percent transfer authority and to reprogram $5.7 million. I am providing this notification consistent with the requirements of sections 206 and 514 of division H of the Consolidated Appropriations Act, 2014 (P.L. 113-76). HHS will transfer and reprogram the funds to carry out the following activities:

Cybersecurity. To address Department-wide cybersecurity needs, HHS plans to transfer approximately $10.6 million from other HHS accounts and reprogram approximately $1.7 million within the Public Health and Social Services Emergency Fund. Funds will support operations costs for the Trusted Internet Connection, which will be implemented fully in FY 2014, and increases to operations and maintenance costs related to a previous critical upgrade carried out in FY 2013.

Ryan White HIV/AIDS Program. The Health Services and Resources Administration (HRSA) plans to transfer $2.1 million and reprogram $4.0 million within the Ryan White HIV/AIDS Program accounts. These actions will increase funding for Part C Early Intervention grants by $4.5 million to mitigate the continuing effect of the FY 2013 sequestration and to address health care needs for vulnerable populations that are no longer funded through Part A. In addition, as a result of Ponce, Puerto Rico, losing its status as a Transitional Grant Area (TGA), HRSA will reallocate $1.6 million from Part A grants to Eligible Metropolitan Areas/TGAs to Part B Grants to States and Territories, as required by the Public Health Service Act.

Enclosed is a table that provides detail on the transfers described above. In the current fiscal environment, the use of this transfer authority is necessary to allow HHS to implement the Department's legally mandated responsibilities effectively. I appreciate the Subcommittee's continued interest in and support of the activities of HHS.

Sincerely,

Kathleen Sebelius

Enclosure

Department of Health and Human Services

FY 2014 Secretary's Transfer

(Amounts in Millions)

All Purpose Table

	FY 2014 Enacted	FY 2014 Operating Level	Secretary's Transfer	Reprogramming	FY 2014 Revised Operating Level
Health Resources and Services Administration					
HIV/AIDS Bureau					
Ryan White AIDS Programs					
Emergency Assistance - Part A	655.876	653.100	-2.115	-1.612	649.373
Comprehensive Care Programs - Part B	1,315.005	1,312.834	-	1.612	1,314.446
Early Intervention Program - Part C	201.079	201.079	2.115	2.350	205.544
Children, Youth, Women, and Families - Part D	75.088	74.395	-	-2.000	72.395
AIDS Dental Services - Part F	13.122	13.089	-	-0.098	12.991
Education and Training Centers - Part F	33.611	33.527	-	-0.252	33.275
Total: Health Resources and Services Administration			-	-	
Centers for Disease Control and Prevention					
Public Health Scientific Services 1/	397.266	396.309	-1.011	-	395.298
Buildings and Facilities	24.000	24.000	-0.228	-	23.772
Total: Centers for Disease Control and Prevention			-1.239	-	
1/ The FY 2014 Enacted level for the CDC includes the transfer of the Business Services Support appropriation to implement the Working Capital Fund.					
National Institutes of Health					
National Cancer Institute	4,923.238	4,917.166	-0.965	-	4,916.221
National Heart, Lung, and Blood Institute	2,988.605	2,979.347	-0.585	-	2,978.762
National Institute of Dental & Craniofacial Research	398.650	398.649	-0.078	-	398.571
Nat. Inst. of Diabetes & Digestive & Kidney Diseases	1,744.274	1,739.895	-0.342	-	1,739.553
National Institute of Neurological Disorders and Stroke	1,587.982	1,583.996	-0.311	-	1,583.685
National Institute of Allergy and Infectious Diseases	4,358.841	4,387.725	-0.855	-	4,386.870
National Institute of General Medical Sciences	2,364.147	2,359.212	-0.464	-	2,358.748
Eunice Kennedy Shriver Nat. Inst. of Child Health and Human Devel	1,282.595	1,279.375	-0.252	-	1,279.123
National Eye Institute	682.077	673.475	-0.134	-	673.341
National Institute of Environmental Health Sciences	665.439	663.769	-0.131	-	663.638
National Institute on Aging	1,171.038	1,168.098	-0.230	-	1,167.868
Nat. Inst. Arthritis & Musculoskeletal & Skin Diseases	520.053	518.748	-0.102	-	518.646
Nat. Inst. on Deafness & Other Communication Disorders	404.049	403.035	-0.079	-	402.956
National Institute of Nursing Research	140.517	140.164	-0.028	-	140.136
National Institute on Alcohol Abuse and Alcoholism	446.025	444.905	-0.087	-	444.818
National Institute of Mental Health	1,446.172	1,415.185	-0.284	-	1,414.901
National Human Genome Research Institute	497.813	496.563	-0.098	-	496.465
National Institute of Biomedical Imaging and Bioengineering	329.172	325.986	-0.065	-	325.921
National Center for Advancing Translational Sciences	633.267	631.677	-0.124	-	631.553
National Center for Complementary and Alternative Medicine	124.298	123.984	-0.024	-	123.960
National Institute on Minority Health and Health Disparities	268.322	267.648	-0.053	-	267.595
John E. Fogarty International Center	67.577	67.408	-0.013	-	67.395
National Library of Medicine	327.723	327.400	-0.064	-	327.336
Office of the Director	1,400.134	1,396.619	-0.275	-	1,396.344
Buildings and Facilities	128.663	128.341	-0.025	-	128.316
Total: National Institutes of Health			-5.668	-	
Substance Abuse & Mental Health Services Administration					
Health Surveillance and Program Support	151.296	150.919	-0.773	-	150.146
Administration for Children and Families					
Child Care and Development Block Grant	2,360.000	2,360.000	-1.754	-	2,358.246
Programs for Children, Youth and Families					
Head Start, current funded	8,598.095	8,598.095	-0.250	-	8,597.845
Child Abuse Discretionary Activities	28.744	28.744	-0.423	-	28.321
Individual Development Account Initiative	19.026	19.026	-0.076	-	18.950
Total: Administration for Children and Families			-2.503	-	
Administration on Community Living					
Aging Network Support Activities	7.461	7.442	-0.036	-	7.406
Alzheimer's Disease Demonstrations	3.800	3.790	-0.018	-	3.772
Lifespan Respite Care	2.360	2.354	-0.012	-	2.342
Elder Rights Support Activities	3.874	3.864	-0.019	-	3.845
Aging and Disability Resource Centers	6.119	6.104	-0.037	-	6.067
Developmental Disabilities Projects of National Significance	8.880	8.857	-0.036	-	8.821
Program Administration	30.035	29.960	-0.158	-	29.802
Total: Administration on Community Living			-0.316	-	

FY 2014 Secretary's Transfer

(Amounts in Millions)

	FY 2014 Enacted	FY 2014 Operating Level	Secretary's Transfer	Reprogramming	FY 2014 Revised Operating Level
Office of the Secretary					
General Departmental Management					
Federal Funds	208.112	207.490	-0.045	-	207.445
Teen Pregnancy Prevention	101.000	100.748	-0.021	-	100.727
Abstinence Education	5.000	4.988	-0.001	-	4.987
Minority Health	56.670	56.528	-0.012	-	56.516
Office of Women's Health	34.050	33.965	-0.007	-	33.958
Minority HIV/AIDS	52.224	52.093	-0.011	-	52.082
Total: General Department Management			-0.097	-	
Office of the National Coordinator for Health IT	**15.556**	**15.517**	**-0.003**	**-**	**15.514**
Public Health and Social Services Emergency Fund					
Cyber Security	41.125	41.125	10.599	1.693	53.417
Medical Reserve Corps	10.672	10.672	0.000	-1.693	8.979
Total: Public Health and Social Services Emergency Fund			10.599	-	

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN HOSPITAL ASSOCIATION, ***et al.,***

Plaintiffs,

v.

SYLVIA M. BURWELL, in her official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES,

Defendant.

Civil Action No. 14-851 (JEB)

ORDER

For the reasons set forth in the accompanying Memorandum Opinion, the Court ORDERS that:

1. Defendant's Motion to Dismiss is GRANTED;

2. Plaintiffs' Motion for Summary Judgment is DENIED; and

3. Judgment is ENTERED in favor of Defendant.

IT IS SO ORDERED.

/s/ James E. Boasberg
JAMES E. BOASBERG
United States District Judge

Date: December 18, 2014

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN HOSPITAL ASSOCIATION, ***et al.,*** **Plaintiffs,** **v.** **SYLVIA M. BURWELL, in her official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES,** **Defendant.**	**Civil Action No. 14-851 (JEB)**

MEMORANDUM OPINION

No one likes the waiting game, and Plaintiffs in this case are no exception. As hospitals that provide services to Medicare patients, they have reimbursement claims languishing in an administrative process that is unable to manage an ever-growing backlog of appeals. Without a change, these hospitals will likely have to wait years for resolution of these claims – and their money. Seeking to break the logjam, Plaintiffs brought this suit against the Secretary of Health and Human Services for an order compelling her to process their administrative appeals in accordance with statutory timelines. They now move for summary judgment, and the government simultaneously moves to dismiss. While the Court sympathizes with Plaintiffs' plight, for the time being the waiting game must go on. HHS's delay in processing their administrative appeals, while far from ideal, is not so egregious as to warrant intervention. The Court, accordingly, will grant Defendant's Motion to Dismiss and deny Plaintiffs' Motion for Summary Judgment.

I. Background

To understand the basis of Plaintiffs' claim here, a brief primer on Medicare reimbursement may prove helpful. After furnishing Medicare-eligible services, health-care providers submit claims for reimbursement to Medicare Administrative Contractors or MACs. See 42 U.S.C. §§ 1395kk-1(a)(1)-(4),1395ff(a)(2)(A). If a claim is denied, a provider may appeal through a four-step administrative process. See id. § 1395ff. First, it may present its claim to the MAC for redetermination, which decision must occur within 60 days. Id. § 1395ff(a)(3). A provider may then appeal a negative redetermination to a Qualified Independent Contractor. A QIC must conduct an "independent, on-the-record review of an initial determination, including the redetermination and all issues related to payment of the claim," and, in so doing, it must "review[] the evidence and findings upon which the [previous determinations were] based," together with "any additional evidence the parties submit or that the QIC obtains on its own." 42 C.F.R. § 405.968(a). The QIC also has 60 days to resolve claims. Id. § 1395ff(c). Both of these stages are overseen by the Centers for Medicare & Medicaid Services (CMS) within HHS.

After these initial determinations, a provider whose claim has been denied may request a hearing before an Administrative Law Judge. See 42 U.S.C. §§ 1395ff(b)(1)(E)(i), (d)(1)(A). The ALJ level of review is overseen by the Office of Medicare Hearings and Appeals (OMHA), a division within the Office of the Secretary that is functionally and fiscally separate from CMS. This is the first opportunity a provider gets for independent review of a denied claim. See Def. MTD & Opp., Att. 1 (Declaration of Nancy Griswold), Exh. 1 (July 10, 2014, Written Testimony) at 3; Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. L. No. 108-173, § 931(b)(2), 117 Stat. 2066, 2398 (2003) ("The Secretary shall assure the independence of administrative law judges . . . . In order to assure such independence,

the Secretary shall place such judges in an administrative office that is organizationally and functionally separate from [CMS].”). ALJs have 90 days to issue a decision from the time appellants request a hearing. See 42 U.S.C. § 1395ff(d)(1)(a). In the last stage of review, an ALJ’s decision may be appealed to the Departmental Appeals Board (DAB). See id. § 1395ff(d)(2). The division of the DAB that actually reviews these claims is the Medicare Appeals Council, referred to as the “MAC” in regulatory provisions. Following the convention of the parties, the Court will refer to it as the “DAB” to avoid confusion with the MACs that conduct initial determinations and redeterminations. The DAB provides the final level of review within HHS, and its decision is considered that of the Secretary, subject to judicial review. See 42 C.F.R. §§ 405.980, 405.1130; Def. MTD & Opp., Att. 4 (Declaration of Constance Tobias), ¶ 1.

Based on these statutory timelines, a Medicare appeal should pass through all four levels of review within a year or so – and for years they did. See Griswold Testimony at 3. Recently, however, the pipeline has become clogged with cases at the ALJ level. Although OMHA has increased its productivity in response – the average number of dispositions per ALJ more than doubled between 2009 and 2013, and OMHA has added seven new ALJs – the workload far outstrips its capacity. See id. at 3-4.

To see just how overworked OMHA is, it is instructive to look at the numbers. Between 2012 and 2013, the backlog of ALJ-level appeals quintupled. See Pl. MSJ, Exh. 3 (Memorandum from Nancy J. Griswold to OMHA Medicare Appellants dated Dec. 24, 2013) at 1. In 2013, for example, OMHA received 350,629 appeals and decided only 79,303 of them. See id., Exh. 2 (OMHA Medicare Appellant Forum) at 16. As of December 2013, it took an average of sixteen months before an ALJ even heard a case, and that wait is expected to continue

to grow along with the queue of pending appeals. See Griswold Memo at 1. Things have gotten so backed up that OMHA has suspended assigning new hearing requests to ALJs (except from Medicare beneficiaries, who appeal through the same process) for at least two years. See id. At the moment, OMHA receives enough appeals every four to six weeks to keep it busy for a year. See Griswold Testimony at 4. The DAB, although not flooded to the same extent, is also receiving more appeals than it can process. See OMHA Forum at 106-08. Based on the increased caseload, the DAB admits that it is "unlikely" that it will "meet the 90-day deadline for issuing decisions in most appeals." Id. at 110.

So what happened? Plaintiffs blame the surge in appeals on the introduction of Medicare Recovery Audit Contractors or RACs. RACs are private entities with whom the Secretary contracts to audit provider-favorable MAC decisions in "post-payment" review. See 42 U.S.C. § 1395ddd(f)(7)(A). These contractors receive a cut of any improper payments they recover and can challenge claims going back as far as three years. See 42 U.S.C. § 1395ddd(h)(1); Statement of Work for the Medicare Fee-for-Service Recovery Audit Program at 9-10, available at http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/recovery-audit-program/downloads/090111racfinsow.pdf. According to Plaintiffs, it is the RACs' over-auditing that has backed up the appeal process: "As Medicare's only contingency-fee-based contractors, RACs have engaged in wide-ranging audits of Medicare claims, frequently questioning the medical judgment of health care providers and denying claims for the types of services that qualify for the largest amount of reimbursement." Pl. MSJ at 3. The way Plaintiffs see it, more meritless post-payment challenges by RACs means more appeals by providers, and more appeals means a longer wait. The agency does not deny that RACs have played a part in the increased appeals, but it also attributes the spike to "more Medicare beneficiaries, increased

use of covered services," and "additional appeals from Medicaid State agencies." Def. MTD & Opp. at 1.

As to the delays, Plaintiffs are not without statutory recourse. The Medicare Act provides for a process referred to as "escalation," by which health-care providers may bypass the QIC, ALJ, and DAB levels of review if those decisionmakers are unable to resolve their claims within the statutorily prescribed timelines. If, for instance, a QIC is unable to complete its review within 60 days, an appellant may "escalate" its appeal to an ALJ. See 42 U.S.C. § 1395ff(c)(3)(C)(ii). If an ALJ, in turn, has not rendered a decision within 90 days, a claimant may escalate to the DAB, id. § 1395ff(d)(3)(A), in which case it is the QIC's decision that is under review. See 42 C.F.R. § 405.1104; 42 C.F.R. § 405.1108(d). On escalated appeal, the DAB has 180 days within which to act – as opposed to its typical 90-day deadline. See 42 C.F.R. § 405.1100(c)-(d). If, however, the DAB cannot render a timely decision, a claimant may bypass it altogether and seek judicial review in federal court so long as its claim meets an amount-in-controversy requirement (currently $1,430). See 42 U.S.C. § 1395ff(d)(3)(B); 42 C.F.R. § 405.1132(b); 42 C.F.R. § 405.1006(c); Medicare Program; Medicare Appeals: Adjustment to the Amount in Controversy Threshold Amounts for Calendar Year 2014, 78 Fed. Reg. 59702-03 (Sept. 27, 2013). Together, these provisions allow that, in the event any level of the appeals process gets too far behind, claimants may leapfrog it and move on to the next stage.

According to Plaintiffs, however, escalation is not the panacea it might seem. This is because they believe ALJ review to be an invaluable step in the appeals process, which they do not wish to forgo. It represents the first opportunity for hospitals to provide oral testimony in support of their cases, and claimants are able to engage with ALJs and respond to questions in real time. See Pl. MSJ, Exh. 11 (Declaration of Ivan Holleman), ¶ 11; id., Exh. 12 (Declaration

of John Geppi), ¶ 14; id., Exh. 14 (Declaration of John Wallace), ¶ 14. Health-care providers are also able to provide written submissions supporting their arguments to the ALJ. See Geppi Decl., ¶ 14. If, however, a party escalates past the QIC and ALJ, the only record available for review is the MAC record. And although the DAB may conduct additional proceedings, it is not required to do so. See 42 C.F.R. § 405.1108(d)(2). Indeed, for escalated claims the DAB has admitted that it will not hold a hearing "unless there is an extraordinary question of law/policy/fact." OMHA Forum at 117. As a consequence, hospitals find that they are most likely to succeed on their appeals at the ALJ level. See, e.g., Geppi Decl., ¶ 13.

Because escalation does not provide sufficient relief, Plaintiffs feel compelled to bring this suit. Those filing are the American Hospital Association, Baxter Regional Medical Center, Covenant Health, and Rutland Regional Medical Center. They seek mandamus relief that would force Defendant Sylvia Burwell, Secretary of HHS, to adjudicate their pending administrative appeals in a timely fashion. An Amicus for Plaintiffs, the Fund for Access to Inpatient Rehabilitation (FAIR), also submitted a brief. FAIR is a corporation comprised of inpatient rehabilitation hospitals and rehabilitation units that have Medicare claims tied up in the appeals process. Plaintiffs now move for summary judgment, and the Secretary moves to dismiss for lack of jurisdiction.

II. Legal Standard

Summary judgment may be granted if "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); see also Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247-48 (1986); Holcomb v. Powell, 433 F.3d 889, 895 (D.C. Cir. 2006). A fact is "material" if it is capable of affecting the substantive outcome of the litigation. See Liberty Lobby, 477 U.S. at 248; Holcomb, 433 F.3d at

895. A dispute is "genuine" if the evidence is such that a reasonable jury could return a verdict for the nonmoving party. See Scott v. Harris, 550 U.S. 372, 380 (2007); Liberty Lobby, 477 U.S. at 248; Holcomb, 433 F.3d at 895. "A party asserting that a fact cannot be or is genuinely disputed must support the assertion" by "citing to particular parts of materials in the record" or "showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact." Fed. R. Civ. P. 56(c)(1). The moving party bears the burden of demonstrating the absence of a genuine issue of material fact. See Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986).

Under Federal Rule of Civil Procedure 12(b)(1), a court must dismiss a claim for relief when the complaint "lack[s] . . . subject-matter jurisdiction." To survive a motion to dismiss under Rule 12(b)(1), Plaintiffs bear the burden of proving that the Court has subject-matter jurisdiction to hear their claims. See Lujan v. Defenders of Wildlife, 504 U.S. 555, 561 (1992); U.S. Ecology, Inc. v. Dep't of Interior, 231 F.3d 20, 24 (D.C. Cir. 2000). A court has an "independent obligation to determine whether subject-matter jurisdiction exists, even in the absence of a challenge from any party." Arbaugh v. Y & H Corp., 546 U.S. 500, 514 (2006). "For this reason 'the [p]laintiff's factual allegations in the complaint . . . will bear closer scrutiny in resolving a 12(b)(1) motion' than in resolving a 12(b)(6) motion for failure to state a claim." Grand Lodge of the Fraternal Order of Police v. Ashcroft, 185 F. Supp. 2d 9, 13-14 (D.D.C. 2001) (alterations in original) (quoting 5A Charles A. Wright & Arthur R. Miller, Federal Practice and Procedure § 1350 (2d ed. 1987)). Additionally, unlike with a motion to dismiss under Rule 12(b)(6), the Court "may consider materials outside the pleadings in deciding whether to grant a motion to dismiss for lack of jurisdiction." Jerome Stevens Pharms. v. FDA, 402 F.3d 1249, 1253 (D.C. Cir. 2005); see also Venetian Casino Resort, LLC v. EEOC, 409 F.3d

359, 366 (D.C. Cir. 2005) ("[G]iven the present posture of this case – a dismissal under Rule 12(b)(1) on ripeness grounds – the court may consider materials outside the pleadings."); Herbert v. Nat'l Acad. of Sciences, 974 F.2d 192, 197 (D.C. Cir. 1992).

III. Analysis

A. Jurisdiction vs. Merits

The first question the Court considers is whether the dispute here raises a jurisdictional issue or can be decided on the merits. This Court has "original jurisdiction of any action in the nature of mandamus to compel an officer or employee of the United States or any agency thereof to perform a duty owed to the plaintiff." 28 U.S.C. § 1361. "Jurisdiction over actions in the nature of mandamus," however, "is strictly confined." In re Cheney, 406 F.3d 723, 729 (D.C. Cir. 2005) (en banc) (internal quotation marks omitted). Mandamus is "drastic," "it is available only in extraordinary situations," and "it is hardly ever granted." Id. (internal quotation marks omitted). To be entitled to mandamus relief, Plaintiffs must show they have "a clear and indisputable right to relief," that the agency "has a clear duty to act," and that there is "no other adequate remedy" available to them. See United States v. Monzel, 641 F.3d 528, 532 (D.C. Cir. 2011) (citing Power v. Barnhart, 292 F.3d 781, 784 (D.C. Cir. 2002)). "The party seeking mandamus," accordingly, "has the burden of showing that 'its right to issuance of the writ is clear and indisputable.'" N. States Power Co. v. U.S. Dep't of Energy, 128 F.3d 754, 758 (D.C. Cir. 1997) (quoting Gulfstream Aerospace Corp. v. Mayacamas Corp., 485 U.S. 271, 289 (1988)). "[E]ven if the plaintiff overcomes all these hurdles," however, "whether mandamus relief should issue is discretionary." Cheney, 406 F.3d at 729.

"In resolving a motion to dismiss an action for relief in the nature of mandamus, courts have characterized the issue as involving both a jurisdictional and a merits inquiry because, in

determining whether the court has jurisdiction to compel an agency or official to act, the court must consider the merits question of whether a legal duty is owed to the plaintiff under the relevant statute." Auburn Reg'l Med. Ctr. v. Sebelius, 686 F. Supp. 2d 55, 62 (D.D.C. 2010), rev'd on other grounds and remanded, 642 F.3d 1145 (D.C. Cir. 2011). "[I]f," therefore, "there is no clear and compelling duty under the statute as interpreted, the district court must dismiss the action. To this extent, mandamus jurisdiction under § 1361 merges with the merits." Cheney, 406 F.3d at 729; In re Medicare Reimbursement Litig., 309 F. Supp. 2d 89, 95 & n.4 (D.D.C. 2004).

Because the inquiries "merge," some district courts in this Circuit have treated the question of a clear and compelling duty on the merits. See, e.g., Banner Health v. Sebelius, 797 F. Supp. 2d 97, 118 n.18 (D.D.C. 2011) ("[I]f dismissal rests on a plaintiff's failure to point to a clear and compelling duty, it should be treated as a dismissal for failure to state a plausible entitlement to relief, not as a dismissal for lack of subject matter jurisdiction."). Others district courts have treated the question jurisdictionally. See, e.g., Nat'l Sec. Counselors v. CIA, 898 F. Supp. 2d 233, 267 n.21 (D.D.C. 2012) ("The D.C. Circuit has held that, to the extent the court must determine whether a 'clear and compelling' duty exists, 'mandamus jurisdiction under § 1361 merges with the merits' because if no 'clear and compelling' duty exists, the claim fails and the court also has no jurisdiction over the claim under 28 U.S.C. § 1361.") (quoting Cheney, 406 F.3d at 729).

In this case, the dual nature of the inquiry means that the Court can resolve Plaintiffs' Motion for Summary Judgment together with Defendant's Motion to Dismiss for Lack of Jurisdiction. This is so because whether HHS's delay is so unreasonable as to warrant relief requires the same analysis as whether the Court has jurisdiction to grant that relief. See Liberty

Fund, Inc. v. Chao, 394 F. Supp. 2d 105, 114 (D.D.C. 2005) ("Whether [Plaintiffs] have, in fact, demonstrated unreasonable delay – and thus, a 'clear right' to relief under the Mandamus Act – is intertwined with the merits inquiry . . . .").

B. Analysis of TRAC Factors

This case, unlike many mandamus actions, does not concern an agency's refusal to act. Instead, the issue here is agency delay. In its analysis, the Court must determine whether such delay is "so egregious" as to warrant relief. See Telecommunications Research & Action Ctr. v. FCC, 750 F.2d 70, 79 (D.C. Cir. 1984) (TRAC). "There is 'no per se rule as to how long is too long' to wait for agency action . . . .'" In re Am. Rivers & Idaho Rivers United, 372 F.3d 413, 419 (D.C. Cir. 2004) (quoting In re Int'l Chem. Workers Union, 958 F.2d 1144, 1149 (D.C. Cir. 1992)). Instead, courts in this Circuit – and the parties here – reference the "hexagonal contours of a standard" identified in TRAC. 750 F.2d at 80. In that case, the D.C. Circuit identified the following six considerations as relevant in evaluating agency delay:

> (1) the time agencies take to make decisions must be governed by a rule of reason; (2) where Congress has provided a timetable or other indication of the speed with which it expects the agency to proceed in the enabling statute, that statutory scheme may supply content for this rule of reason; (3) delays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake; (4) the court should consider the effect of expediting delayed action on agency activities of a higher or competing priority; (5) the court should also take into account the nature and extent of the interests prejudiced by delay; and (6) the court need not find any impropriety lurking behind agency lassitude in order to hold that agency action is unreasonably delayed.

Id. (citations and internal quotation marks omitted). These factors "are not 'ironclad,' but rather are intended to provide 'useful guidance in assessing claims of agency delay.'" In re Core Commc'ns, Inc., 531 F.3d 849, 855 (D.C. Cir. 2008) (quoting TRAC, 750 F.2d at 80). Indeed,

"[e]ach case must be analyzed according to its own unique circumstances. . . . Each case will present its own slightly different set of factors to consider." Air Line Pilots Ass'n, Int'l v. Civil Aeronautics Board, 750 F.2d 81, 86 (D.C. Cir. 1984).

For the sake of clarity, the Court will reorder the factors to fit the specifics of this case. First, it will address the Secretary's failure to comply with statutory deadlines (factors one and two). Then, it will examine the consequences of non-intervention to Plaintiffs and the public (factors three and five). Next, it will consider the effect intervention might have on competing agency priorities (factor four). Finally, it will weigh the Secretary's good faith in addressing the problem (factor six).

1. *Failure to Comply with Statutory Deadlines*

The first TRAC factors ask whether the agency's timeline of action is "governed by a 'rule of reason,'" the content of which may be found in a "timetable or other indication . . . in the enabling statute." See 750 F.2d at 80. The Secretary concedes that the 90-day statutory "timetable supplies the applicable rule of reason" in this case, and she does not deny that ALJs are in violation of this rule. See Def. Rep. at 14.

Emphasizing that these have been called the "most important" factors, see In re People's Mojahedin Org. of Iran, 680 F.3d 832, 837 (D.C. Cir. 2012) (citation omitted), Plaintiffs seize on the agency's failure in this regard and argue that it alone justifies intervention. They liken this case to People's Mojahedin, where the D.C. Circuit found that a twenty-month failure to act on a 180-day statutory deadline "plainly frustrate[d] the congressional intent and cut[] strongly in favor of granting [the] mandamus petition." Id. at 837. As was the case there, Plaintiffs argue that "[t]he specificity and relative brevity" of the deadlines here "manifest[] the Congress's intent" that HHS act promptly on appeals. See Pl. MSJ at 20 (quoting People's Mojahedin, 680

F.3d at 837). The deadline here, they point out, is shorter than in People's Mojahedin; the delay is longer; and the agency has affirmatively declared it will not meet its deadlines in the future. "In certain situations, administrative delays may be unavoidable," Plaintiffs concede, but "extensive or repeated delays are unacceptable and will not justify the pace of action." Id. at 21 (quoting Muwekma Tribe v. Babbitt, 133 F. Supp. 2d 30, 36 (D.D.C. 2000)); see also Am. Rivers, 372 F.3d at 419 (While there "is 'no per se rule as to how long is too long' to wait for agency action . . . , a reasonable time for agency action is typically counted in weeks or months, not years.") (quoting Chem. Workers, 958 F.2d at 1149).

Although the Court agrees that HHS has violated its statutory framework, this conclusion "does not, alone, justify judicial intervention." In re Barr Labs., Inc., 930 F.2d 72, 75 (D.C. Cir. 1991). As will become clear below, competing policy and budgetary concerns distinguish this case from People's Mojahedin and reduce the heft of these first two factors.

2. *Consequences of Non-Intervention*

The Court next examines the possible effects of non-intervention. The third TRAC factor looks to the consequences the public faces if the Court does not intervene, and the fifth assesses the "nature and extent of the interests prejudiced by delay." 750 F.2d at 80. In this regard, "delays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake." Id. Plaintiffs address these two together, claiming that "the prejudice suffered by the Plaintiff hospitals is exactly the harm courts have found particularly well-suited for mandamus relief: harm to patient health and welfare." Pl. MSJ at 21.

Their argument runs as follows: Hospitals are deeply out of pocket due to denied claims. Covenant's hospitals, for instance, have over $7 million worth of appeals currently pending at the ALJ level. See Geppi Decl., ¶ 8. Baxter has so much tied up in appeals that it has been

unable to update its equipment or provide necessary repairs to its facilities, and its bond rating is at risk. See Holleman Decl., ¶¶ 9, 14, 17. Overall, the holdups have forced health-care providers to reduce costs, eliminate jobs, forgo services, and substantially scale back. See Wallace Decl., ¶ 19; Geppi Decl., ¶¶ 18, 19; Holleman Decl., ¶¶ 14, 16. While these are indisputably economic consequences, Plaintiffs conclude that in a case like this, where there is "a nexus between human welfare and 'economic' considerations," the ultimate consequences on "health services and facilities" "weigh[] in favor of compelling agency action based on unreasonable delay." Muwekma Tribe, 133 F. Supp. 2d at 39; Air Line Pilots Ass'n, 750 F.2d at 86 (finding that the third TRAC factor weighed in favor of relief where agency had delayed in adjudicating claims for unemployment-assistance payments).

Even if Plaintiffs are correct about the nexus, they point to very few specific services that are actually less available to the public as a result of the delays. Besides generalized concerns that hospitals may have to scale back, the best they can do is to note that some rehabilitation facilities represented by Amicus have been "forced to avoid admitting certain types of patients" – *i.e.*, those "with a lower extremity joint replacement or debilitated physical condition following an extended acute care hospital admission" – due to uncertainty about timely reimbursement. See Amicus Brief at 23. While these are real consequences to health and welfare, they are not the kind of immediate and undisputed dangers that have weighed heavily in the TRAC analysis in other cases. See, e.g., Pub. Citizen Health Research Group v. Comm'r, Food & Drug Admin., 740 F.2d 21, 34 (D.C. Cir. 1984) ("All scientific evidence in the record points to a link between salicylates and Reye's Syndrome . . . ."); Pub. Citizen v. Heckler, 602 F. Supp. 611, 613 (D.D.C. 1985) ("Officials at the highest levels of [the agency] have concluded that certified raw milk poses a serious threat to the public health.").

Plaintiffs' argument, moreover, ignores the bigger picture. Nearly everything HHS does affects human health and welfare – and that context matters. As the D.C. Circuit has noted, "[A]lthough this court has required greater agency promptness as to actions involving interests relating to human health and welfare, . . . this factor alone can hardly be considered dispositive when, as in this case, virtually the entire docket of the agency involves issues of this type." Sierra Club v. Thomas, 828 F.2d 783, 798 (D.C. Cir. 1987). For this reason, the third and fifth TRAC factors weigh, if at all, only very lightly in favor of granting relief. This now leads to the related and most significant consideration in this case: competing priorities.

3. *Competing Priorities*

Here lies the knotty heart of this case. In analyzing the fourth TRAC factor, the Court must consider "the effect of expediting delayed action on agency activities of a higher or competing priority." 750 F.2d at 80. On this front, the Secretary likens her situation to Barr Labs., a case in which the D.C. Circuit rejected a petition for mandamus against the Food and Drug Administration for prompt resolution of generic drug applications. That case resembles the present one in several key respects. First, the FDA in Barr Labs. had also violated a statutory deadline. See 930 F.2d at 74. Second, it had done so in similar orders of magnitude – taking up to 669 days to resolve applications it should have decided in 180. See id. Finally, the FDA's inaction there resulted in "fewer resources for other aspects of health care." Id. at 75. The Circuit, accordingly, faced the same question the Court does here: "not whether the [agency's] sluggishness has violated a statutory mandate," or whether its inaction affects health and welfare, "but whether [the Court] should exercise [its] equitable powers to enforce the deadline." Id. at 74. The Circuit declined to do so, and its rationale is instructive.

"Equitable relief," the Circuit noted, "particularly mandamus, does not necessarily follow a finding of a violation: respect for the autonomy and comparative institutional advantage of the executive branch has traditionally made courts slow to assume command over an agency's choice of priorities." Id. That is why the effect on health and welfare was "irrelevant." Id. at 75. As is the case here, moreover, "[a]gency officials . . . [had] not just been 'twiddl[ing] their thumbs.'" Id. (quoting Board of Trade v. SEC, 883 F.2d 525, 531 (7th Cir. 1989)). In refusing to grant relief, the Circuit emphasized that it "ha[d] no basis for reordering agency priorities," and that "[t]he agency is in a unique – and authoritative – position to view its projects as a whole, estimate the prospects for each, and allocate its resources in the optimal way." Id. at 76. "Such budget flexibility as Congress has allowed the agency is not for [the Court] to hijack," it concluded. Id. "Perhaps," the Circuit observed, "Congress should earmark more funds specifically to the . . . program, but that is a problem for the political branches to work out." Id. at 75 (citation omitted). Because it was not the Circuit's place to enter into questions of agency priorities and budgetary constraints, it refused to do so. Id.; see also United Mine Workers, 190 F.3d at 552-53 (refusing to compel agency to act in face of eight-year delay that violated statutory requirements because expediting one rulemaking "might well delay rulemaking for other contaminants that are at least as dangerous"); Chao, 394 F. Supp. 2d at 120 ("The [D.C. Circuit has] suggested that competing priorities would be the most significant factor in any case where the agency delay was due to 'lack of resources' and the agency applied a 'first-come' approach.") (quoting Mashpee Wampanoag Tribal Council, Inc. v. Norton, 336 F.3d 1094, 1100 (D.C. Cir. 2003)).

These conclusions in regard to the FDA strike as strong a note with HHS in an area similarly constrained by budgetary concerns and competing agency priorities. As in Barr Labs.,

HHS's delays might injure hospitals and possibly affect health and welfare, but they do so as to all Medicare provider-appellants equally. See Def. MTD & Opp. at 21. HHS, OMHA, and the DAB have fixed resources to address the unprecedented appeals they are currently facing. See Griswold Decl., ¶ 3; Tobias Decl., ¶ 6. And although the Secretary has limited authority to transfer funds – the details of which are discussed below – myriad other concerns compete for any funding she might bring to the problem. See Def. Rep. at 17 (noting examples such as operating the health-insurance Marteplace and housing unaccompanied alien children who arrive in the United States). This is precisely the kind of conundrum the D.C. Circuit has cautioned courts against trying to solve. See Barr Labs., 970 F.2d at 76.

Plaintiffs are not persuaded. They counter that there are several steps the Secretary could take to rectify the situation. For instance, Plaintiffs claim, she could avail herself of funds within HHS to hire more ALJs. See Pl. Opp. & Rep. at 17. As the Secretary explains, however, OMHA is funded through its own appropriation. See Department of Health & Human Services Appropriations Act, 2014, Pub. L. No. 113-76, Div. H, Title II, 128 Stat. 363, 380 (Jan. 17, 2014). Transferring money into this appropriation requires authorization by Congress. See 31 U.S.C. § 1532 ("An amount available under law may be withdrawn from one appropriation account and credited to another or to a working fund only when authorized by law."). And while it is true that the 2014 HHS Appropriations Act authorizes the Secretary to make certain transfers, it narrowly cabins that authority. Transfers between appropriations cannot exceed 1% of any discretionary Department fund or 3% of a receiving appropriation. See 2014 HHS Appropriations Act § 206, 128 Stat. 382 ("Not to exceed 1 percent of any discretionary funds . . . which are appropriated for the current fiscal year for HHS in this Act may be transferred between appropriations, but no such appropriation shall be increased by more than 3 percent by any such

transfer."). In OMHA's case, 3% of its $83,381,000 appropriation in 2014 would be less than $2.5 million. See Def. Rep. at 20. Such a meager bump in funding would do little to stanch the tide of appeals.

Plaintiffs offer a second option: the Secretary might "reprogram" funds in order to address the backlog. This suggestion, however, is no more helpful than the first. Reprogramming is generally a non-statutory arrangement by which an agency utilizes funds in an appropriation account for purposes other than those contemplated at the time of appropriation. See 1 Gov't Accountability Office, Principles of Federal Appropriations Law at 2-30 (3d ed. 2004). In other words, reprogramming merely shifts funds within an appropriation – an action that would not help Plaintiffs since it is the lack of funds within OMHA that is causing the problem.

Plaintiffs offer one final financial suggestion: force the Secretary to seek greater appropriations for OMHA. They note that in the same legislation in which Congress created OMHA, it also ensured that the Secretary could fund new ALJs. Specifically, Congress allowed that "[i]n addition to any amounts otherwise appropriated, to ensure timely action on appeals before [ALJs] and the [DAB] consistent with [statutory deadlines], there are authorized to be appropriated . . . to the Secretary such sums as are necessary for fiscal year 2005 and each subsequent fiscal year to," among other things, "increase the number of [ALJs]" and "increase the staff of the [DAB]." MMA § 931(c), 117 Stat. 2398–99. Plaintiffs argue that the Secretary could use this authorization to seek funding sufficient to meet the problem, and they invite the Court to force the Secretary to do so. See Pl. Opp. & Rep. at 19.

The Court declines that invitation. To begin, mandamus jurisdiction is not a license to intermeddle, and the Court is loath to horn in on the problem-solving efforts of the other two

branches of government. Congress funds OMHA, Congress created the RAC program, and Congress is aware of the inundation of appeals – indeed, it has recently held hearings on the subject. See Nancy Griswold, Testimony before the House Oversight and Government Reform Subcommittee on Energy Policy, Health Care and Entitlements, C-SPAN 11:55-13:35 (July 11, 2014), available at http://www.c-span.org/video/?320374-1/hearing-medicare-appeals-process. HHS and Congress are actively discussing what might be done about the glut of appeals. So what might the Court do? It makes little sense to force the Secretary to ask Congress for funding to solve a problem of which Congress is well aware. At best, that would be an empty gesture, at worst judicial overstepping.

Plaintiffs are not done yet. Finally, and perhaps tellingly, they claim that HHS should "rein in" RAC audits. See Pl. MSJ at 25. At the end of the day, this appears to be their true aim in bringing suit. Although the other potential remedies are urged, the RACs are Plaintiffs' *bête noire*. This suggestion, however, is no more helpful than the others. As noted above, the RAC program was created by Congress with the purpose of recouping Medicare overpayments. See, e.g., CMS, Recovery Auditing in Medicare and Medicaid for Fiscal Year 2012 at iv-v, 11, available at http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/Downloads/Report-To-Congress-Recovery-Auditing-in-Medicare-and-Medicaid-for-Fiscal-Year-2012_013114.pdf. Although Medicare depends on prompt payment and the presumed honesty and accuracy of providers, Congress concluded that an outside check was necessary to discourage some from seeking to recover improper payments. See Def. MTD & Opp. at 23. RACs were introduced to serve as that check and have been successful in their role, recouping, for instance, $2.3 billion in 2012. See Recovery Auditing at iv-v, 11.

Plaintiffs counter that this "success" is really just the result of overzealous auditing. According to one survey, hospitals have reported RAC denials being overturned 66% of the time on appeal. See Pl. MSJ, Exh. 5 (RAC Survey) at 4, 55. This, they take, as evidence that the Secretary is not doing enough to limit the scope of RAC activity and thereby reduce the influx of appeals. See Pl. Opp. & Rep. at 24. Plaintiffs' data, however, also reveals that those hospitals that won two-thirds of appealed RAC denials only filed appeals in half of the cases – which means that only a third of all reported RAC denials in that survey were ultimately overturned. See RAC Survey at 4. More to the point, whether this or some other ratio of overturned RAC denials reveals auditing excess is a question fraught with policy considerations best left to the judgment of the Secretary and Congress. To the extent that the RAC program is the cause of the delays, it was created by Congress and should be addressed by the Secretary and Congress together.

In the end, here is the state of affairs: OMHA has been saddled with a workload it cannot, at present, possibly manage. Congress is well aware of the problem, and Congress and the Secretary are the proper agents to solve it. In such situations – where an agency is underfunded and where it is processing Plaintiffs' appeals on a first-come, first-served basis – the Court will not intervene. See Chao, 394 F. Supp. 2d at 120. TRAC factor four, therefore, weighs heavily against intervention.

4. *Bad Faith*

Lastly, under TRAC factor six, "the good faith of the agency in addressing the delay weighs against mandamus." Chao, 394 F. Supp. 2d at 120; In re Am. Fed'n of Gov't Employees, AFL-CIO, 837 F.2d 503, 507 (D.C. Cir. 1988) (refusing mandamus relief where agency showed "marked improvement in managing its docket, and there [was] little reason to believe" a court

order "necessary to sustain that improvement or . . . helpful in spurring greater effort"). Here HHS has taken modest steps to increase ALJ work capacity: it is moving to electronic processing, has added ALJs, provided support for ALJs, and offered alternative adjudication options. See Def. MTD & Opp. at 8-10. Plaintiffs criticize these efforts. They claim that such measures do not establish good faith, considering the fact that even the Secretary acknowledges that they will not solve the backlog problem. See, e.g., Pl. Opp. & Rep. at 20-21. That an agency's efforts do not offer a perfect resolution, however, does not render them "bad faith," and "the absence of bad faith" itself "is relevant to the appropriateness of mandamus." Barr Labs., 930 F.2d at 76 (citing Monroe Commc'ns, 840 F.2d at 946-47). These steps, while not substantial, are a move in the right direction. The Court, accordingly, finds that TRAC factor six weighs somewhat against intervention.

* * *

No one denies that OMHA's ALJs are unable to render decisions in accord with the statutory guidelines laid out by Congress. No one denies that this is a problem in need of a fix. This Court, however, is not in a position to provide that fix. Although a superficial accounting might reveal a 2-2 tie among the factor groups, HHS's budgetary constraints, its competing priorities, and its incipient efforts to resolve the issue together dictate that mandamus is not warranted. This conclusion is bolstered by the fact that Congress is aware of the situation and is in a position to address the problem. The Court hopes that the Secretary and Congress will continue working together toward a solution and that OMHA will receive the resources necessary to fulfill its obligations. Hospitals that are owed reimbursement should not be indefinitely deprived of funds. The Court cannot predict whether, over time, if HHS and

Congress cannot adequately address the overflow of appeals, the TRAC factors might shift toward Plaintiffs. In the meantime, they will have to wait along with everyone else.

IV. Conclusion

For the foregoing reasons, the Court will grant Defendant's Motion to Dismiss and deny Plaintiffs' Motion for Summary Judgment. A separate Order so stating will issue this day.

/s/ James E. Boasberg
JAMES E. BOASBERG
United States District Judge

Date: December 18, 2014

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN HOSPITAL ASSOCIATION, *et al.*, Plaintiffs, v. SYLVIA M. BURWELL, in her official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES, Defendant.	Civil Action No. 1:14-CV-851-JEB

NOTICE OF APPEAL

Notice is hereby given that the American Hospital Association, Baxter Regional Medical Center, Covenant Health, and Rutland Regional Medical Center, plaintiffs in the above-named case, hereby appeal to the United States Court of Appeals for the District of Columbia Circuit from the District Court's judgment dismissing Plaintiffs' claims (DE 20) entered in this action on the 18th day of December, 2014.

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